

Draft Technical Brief

Number XX

Critical Analysis of the Evidence for Resident Safety Practices in Nursing Home Settings

Prepared for:

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Suggested Citation: <Authors>. Critical Analysis of the Evidence for Patient Safety Practices in Nursing Home Settings. Technical Brief. <#>. (Prepared by the <EPC Name> Evidence-based Practice Center under Contract No. <##>.) AHRQ Publication No. XX-EHCXXX-EF. Rockville, MD: Agency for Healthcare Research and Quality. <Month Year>. www.effectivehealthcare.ahrq.gov.

None of the investigators has any affiliation or financial involvement that conflicts with the material presented in this report.

Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: (redacted for peer review).

Key Informants

In designing the study questions, the EPC consulted a panel of Key Informants who represent subject experts and end-users of research. Key Informant input can inform key issues related to the topic of the Technical Brief. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The Task Order Officer and the Evidence-based Practice Center work to balance, manage, or mitigate any conflicts of interest.

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Prior to publication of the final evidence report, the EPC sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report does not necessarily represent the views of individual reviewers.

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about healthcare. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and healthcare services to meet the needs of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments and Comparative Effectiveness Reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care. Technical Briefs are the most recent addition to this body of knowledge.

A Technical Brief provides an overview of key issues related to a clinical intervention or health care service—for example, current indications for the intervention, relevant patient population and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions. The emphasis, therefore, is on providing an early objective description of the state of science, a potential framework for assessing the applications and implications of the new interventions, a summary of ongoing research, and information on future research needs.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly, while Technical Briefs will serve to inform new research development efforts.

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Structured Abstract

Background. Resident safety issues are common in nursing homes. Relevant literature reports a range of poor clinical outcomes thought to be preventable if specific care processes were consistently implemented.

Purpose. To summarize relevant literature, including identifying safety issues and contextual factors that affect safety in nursing homes; potential hospital safety interventions of relevance to nursing homes; literature on safety interventions evaluated in nursing homes; barriers and facilitators of interventions; and future directions for safety research in this setting.

Methods. We had conversations with Key Informants representing multiple stakeholder groups. We conducted literature searches to identify recent systematic reviews of interventions addressing safety areas in nursing homes. We also searched the literature for newly published studies of interventions.

Findings. Nursing home resident safety results from the interplay of resident characteristics and needs within the context of staffing and programmatic decisions that are influenced by various payment and regulatory models. Safety outcomes, per se, have not been well studied in nursing homes; however, quality of care outcomes have been studied, in some cases extensively, and may serve as contributing factors to safety outcomes. Nursing homes must find the balance between preserving person-centeredness and resident autonomy while ensuring safety, quality of care and quality of life for residents. Key safety issues are adverse events such as falls, pressure ulcers, infection, medication errors/adverse drug events, including inappropriate use. Other elements are potentially contributing factors to safety and include catheter left in bladder, and physical restraints as well as documented conditions including unintentional weight loss, decline in activities of daily living, fecal/urinary incontinence, depressive symptoms, and pain. More than 60 recent systematic reviews evaluated nursing home safety-related interventions and typically reported mixed findings in studies of poor to moderate quality. Evidence is lacking on the degree to which national uptake of efficacious interventions targeting adverse events or factors that may lead to adverse events has occurred, with barriers including staffing costs needed to implement the interventions and low quality evidence. Little evidence suggests that hospitals have significantly improved safety in many domains that are important to care of nursing home residents, whose vulnerability and complexity make them markedly different from most hospital patients. Future research needs include understanding the relationship between adherence to quality of life and person-centered care standards and incidence of adverse events, overcoming barriers to implementing proven interventions, and improving safety event reporting.

Background

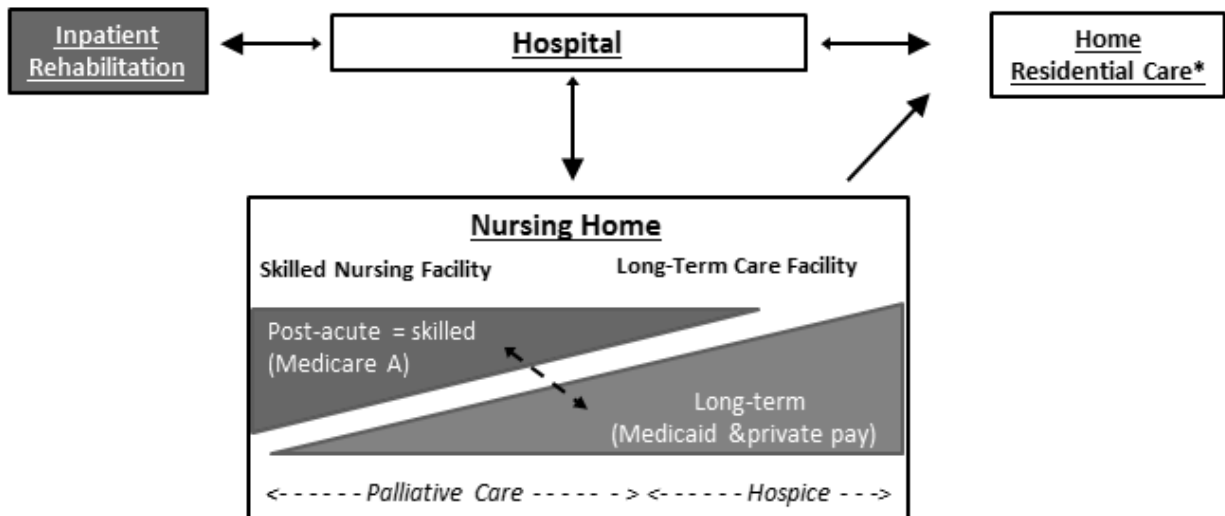
The Structure of the Nursing Home

An estimated 1,383,700 individuals live in nursing homes and 713,300 in residential care communities in the United States.¹ The term “nursing home” can denote a wide range of facilities that provide one or multiple levels of care (Figure 1, Table 1). For the purposes of this technical brief, we use the term “nursing home” to mean a facility in which any of the following types of care are provided:

- Skilled nursing care after hospitalization (also called “post-acute care” or “short-stay rehabilitation”; but not inpatient rehabilitation in which more intensive therapy is provided, e.g., higher number of therapy hours per patient)
- Other nursing care in a long-term care setting (also called “long-term care” or “long-stay”)
- Both skilled nursing and long-term care (with or without additional residential living such as assisted or independent living)

Given the wide range of services provided, the characteristics of residents may differ widely both between nursing homes and within a given nursing home. Post-acute care residents are admitted from the hospital with the goal of resolving acute medical illness and its sequelae in order to return to a prior home or residential setting. In contrast, the majority of residents in long-term care, who arrive either from the community or after post-acute care, do not return to the community. Therefore, the safety issues of these populations, as well as the interventions that may effectively target those issues, will vary.

Figure 1. Care settings and transitions in care



Directional arrows denote transitions in care, which can increase a resident’s risk for adverse events (e.g., medication changes and errors, communication gaps between providers, delirium). The top panel depicts the post-acute population admitted from the hospital (also called skilled or short-stay). The bottom panel represents the long-term care residents (also called long-stay). Post-acute residents may be discharged home or to residential care. If they require more assistance and ongoing nursing care, they are typically discharged to long-term care, often within

the same long-term care facility. Residential care may include assisted living and/or independent living, which is most often in a separate setting from a nursing home but sometimes may include a nursing home (e.g. in life care communities and continuing care retirement community (CCRC), in which care for residents spans the entire spectrum).

Table 1. Definitions of commonly used terms in the literature and this technical brief

Resident	An individual living in a nursing home, either temporarily or permanently.
Nursing home (Nursing facility)	Facility in which nursing care is provided, either long-term care, post-acute care, or both.
Long-term care	Health-related care and services (above the level of room and board), needed daily due to a mental and/or physical condition. Residents may be called “long-stay”
Post-acute care	Skilled nursing care and/or rehabilitation services for residents who require such care because of injury, disability, or illness with intent of returning to their prior community living arrangement. Some post-acute rehabilitation may also be provided in rehabilitation hospitals. Residents may be called “skilled” or “short-stay.”
Skilled nursing facility	A facility engaged primarily in providing post-acute care (i.e., skilled nursing care and rehabilitation services) for residents who require such care because of injury, disability, or illness. Also called short-stay facilities. 90% of facilities are dually certified to provide both post-acute and long-term care.
Assisted living	A facility combining housing, personalized supportive services, and health care designed to meet the individual needs of persons who need help with the activities of daily living, but do not need the care level provided in a nursing home.
Independent living	Communities that provide housing in apartment complexes, condominiums, or even free-standing homes. Meals may be provided.
Residential care	Nonspecific term which may include independent living, assisted living, and/or dementia care within assisted living.
Care home	Term used outside of the United States which may include any or all of the spectrums of care (post-acute care, long-term care, assisted living, independent living).

Nursing Home Safety

The Agency for Healthcare Research and Quality (AHRQ) defines safety as “a type of process or structure that reduces the probability of an adverse event.”² An adverse event is defined as harm to a resident as a result of medical care or in a health care setting.³ Studying adverse events and interventions that may prevent them and/or promote safety is an important but complex undertaking, particularly in settings with vulnerable populations (typically, but not exclusively, defined as the elderly, people with economic disadvantages, the uninsured, low-income children, the homeless, racial and ethnic minorities, and those with chronic health conditions.⁴⁻⁶

In 2014, an average of 7.96 deficiencies in care per nursing home was reported in state surveys. The most common deficiencies were for failures in infection control, accident environment, food sanitation, quality of care, and unnecessary drugs. More than 20 percent of facilities had a deficiency for actual harm or jeopardy. An estimated mean 1.5 falls/bed/year occur in long-term care facilities, with 4 percent of these resulting in fracture and 11 percent resulting in serious injuries such as lacerations and head trauma.^{7,8} Additionally, Federal deficiency data from 2012 (Table 2) demonstrates an average of 6.1 deficiencies per facility. These data may include both short and long stay care. Specific to short-stay residents, one in five older adults admitted to skilled nursing facilities (SNFs) after hospitalization experience adverse events, and 60 percent of these are preventable.³ Per the 2014 Office of the Inspector General

(OIG) report, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, among the 10 percent of residents harmed by adverse events, half were readmitted to the hospital for treatment, resulting in \$2.8 billion of Medicare spending.³

Table 2. Facility characteristics

Facility Characteristics* (n=15,683 Nursing Homes)	Proportion Nationwide
Percent Dually-Certified (Medicare and Medicaid)	91.4%
Average Occupancy Rate	82.7%
Percent 50-99 Beds	36.5%
Percent 100-199 Beds	44.1%
Percent For-Profit Status	69.0%
Average Total Staffing Hours per Resident per Day (HPRD)	4.12
Average Licensed Nurse Staffing (HPRD)	1.67
Average Nurse Aide Staffing Level (HPRD)	2.45
Average Number of Health Deficiency Citations per facility	6.1
Percent with Citations for Immediate Jeopardy or Actual Harm	3.4%
Percent with Citations for Substandard Quality of Care	3.4%
Percent with Citation for Use of Restraints	6.0%
Percent with Deficiency for Failure to Treat/Prevent Pressure Ulcers	14.6%

*Based on Centers for Medicare & Medicaid Services data for 15,683 nursing homes, Nursing Home Data Compendium 2012 Edition.⁹ Staffing Data reflects 2015 national average based on medicare.gov/nursinghomecompare. Licensed Staff comprises Licensed Vocational Nurse (LVN), Licensed Practical Nurse (LPN) and Registered Nurse (RN). HPRD=Hours per Resident per Day

Nursing home residents are susceptible to adverse events for a number of reasons including a highly vulnerable population (debilitated after hospitalization for acute illness, chronically frail, cognitively and/or physically impaired); and transitions in care between providers and settings. Because of the uniqueness of the nursing home setting and its population, studying the effectiveness of safety interventions in the nursing home is particularly important.

Approaches to Studying Nursing Home Safety

Three primary approaches to studying nursing home safety have been employed, each with attendant strengths and weaknesses. Randomized controlled trials (RCTs), generally considered the gold standard in intervention research, may be employed to test specific interventions. RCTs in nursing homes may include randomization at the resident, unit or facility level. They run the risk, however, of lacking generalizability and, as importantly, of testing interventions that are not feasible with typical settings and staffing. Furthermore, RCTs implemented by trained research staff under optimal care conditions also may not address the feasibility of translating efficacious interventions into daily nursing home care practice. Most notably, the few interventions that have measured the staff time required for intervention implementation show that more staff time is often necessary relative to usual care practices to provide the intervention (see GQ4).

Examples of RCTs in nursing homes include staff training and multicomponent interventions for applying dressings and repositioning for pressure ulcers,¹⁰⁻¹⁶ exercise and other modalities to prevent mobility decline and falls prevention,^{1, 17-26} scheduled toileting interventions to improve urinary incontinence, and improvements in mealtime and between-meal nutritional care practices to promote food and fluid intake.²⁷⁻²⁹

Second, prospective, but uncontrolled evaluations of safety interventions have been used to study efforts to provide incentives for nursing homes to improve care quality, general staff training interventions, and more focused staff training to improve specific outcomes such as unintentional weight loss, urinary incontinence, and hospital readmissions.³⁰⁻³² Studies using this

second approach can suffer limitations including lack of follow-up data, small sample sizes, limited generalizability, and the absence of an appropriate comparison group.

Finally, many studies of nursing home safety have been conducted as secondary analyses of existing data sets, which may or may not have been collected for the purpose of assessing safety. Secondary analyses typically include data from a large number of nursing homes most frequently collected through the self-report of facility staff. The most commonly cited data are derived from the Minimum Data Set (MDS) assessment, which is required by the Centers for Medicare & Medicaid Services (CMS) for short and long-stay nursing home residents nationwide.³³ The MDS is intended to assess comprehensively multiple aspects of a resident's functional status and must be completed for all residents routinely. In many studies, MDS data are compared to other publicly-available data such as nursing home self-reported staffing levels (licensed nurses and nurse aides), deficiencies or citations for quality problems issued by state or federal surveyors, and/or claims data to reflect health care utilization.³⁴ Use of these data has been important for identifying relationships between structural factors such as staffing and ownership, and rates of adverse safety outcomes, including pressure ulcers, falls and health care utilization.^{35, 36} While an important source of data, the MDS was not designed for research on safety issues, and limitations include that it is difficult to identify specific care processes that may provide a causal link or explanation for the relationship of structural factors to the clinical outcomes. The self-reported nature of the data also raises concerns.³⁷

Sources of Data for Assessing Nursing Home Safety

Each of the designs above uses different types of data, and each source of data has strengths and limitations. Four primary data sources (Table 3) have been used to measure nursing home quality and safety: (1) Resident and facility-level data self-reported by nursing home care providers; (2) Medicare & Medicaid claims data; (3) Medical record reviews by external evaluators; and, (4) direct observations of care delivery and/or resident/family interviews. Detailed descriptions of these data sources are available in the Appendix A.

Table 3. Strengths and weaknesses of common data sources for studying safety

Data Source	Strengths	Limitations
Nursing Home Self-Reported Data	<ul style="list-style-type: none"> • Large, publicly reported dataset (more than 15,000 Medicare and Medicaid certified nursing homes contribute data) • Updated quarterly • Common set of questions to facilitate comparability • Standardized resident assessments to minimize bias (Version 3.0) 	<ul style="list-style-type: none"> • Potential biases associated with self-reporting (over or under estimation of clinical conditions) • Potential inaccuracies • Potential for interrater variation and recall bias • Does not capture all potential adverse events • Care processes related to safety not directly measured
Claims Data	<ul style="list-style-type: none"> • Useful for adverse event detection and detection of potential care omissions • Useful for assessing medication and other care utilization • Largely valid and reliable data • Linkage to other data sets 	<ul style="list-style-type: none"> • Limited data for Medicare HMO residents • Care processes related to safety not directly measured • Reporting of care received but not necessarily care needed • Limited information on diagnoses • Limited clinical data
Medical Record Review	<ul style="list-style-type: none"> • Standardized protocols to promote rigorous data collection and analysis • Potentially improved accuracy in assessing care processes related to safety 	<ul style="list-style-type: none"> • Labor intensive • High level of clinical training needed • Potential for limited reproducibility • Potential for inaccuracies in medical record data • Potential for missing or incomplete medical record data
Direct Observation of Care and Resident Interviews	<ul style="list-style-type: none"> • Standardized protocols to promote accuracy • Use of third-party observers to minimize bias • Methods to promote reliability and validity of protocols • Ability to directly measure care processes related to safety 	<ul style="list-style-type: none"> • Potential for recall or observer bias or interrater variation • Labor intensive • Resident cognitive state may affect ability to respond to some types of interview questions

HMO-health maintenance organization

Technical Brief Objectives

The goals of the Technical Brief are to provide an objective description of the state of the science, identify a potential framework for assessing the applications and implications of the intervention, summarize ongoing research, and present research gaps. A Technical Brief is not a comprehensive systematic review and does not summarize results or conclusions of existing research. Rather, it should provide the reader with an overview of available research, practice and to some degree, perspective, around a given clinical intervention. The purpose of this brief is to inform understanding of the evidence associated with safety issues and safe care in the nursing home.

As such, this report describes the state of the literature on safety practices in nursing home settings. The breadth of the literature on this topic makes it atypical for a Technical Brief, and thus we made some modifications to the process. For example, a large number of systematic reviews of a large primary literature base have been published on a range of nursing home safety topics, and our review focused on summarizing those reviews in terms of the numbers and types of studies included. As is the expectation for Technical Briefs, we provide only limited information on conclusions. We supplement these findings with a tabulation of new studies addressing nursing home safety practices in key areas of interest published after these systematic

reviews. In addition, we engaged stakeholders to augment the findings from the literature and inform the summary of contextual issues, barriers to implementation of safety-related interventions, and potential challenges.

It is important to note that, based on the AHRQ definition of safety, the research literature potentially related to safety – including contributors to safety issues – could include a broad range of clinical outcomes (see Scope). In fact, sufficient data are published to warrant separate complete systematic reviews for most of these individual measures, even though prior studies focused on “care quality” rather than “safety” issues. Thus, we provide a very high level overview of the topic, and do not attempt to fully review the full body of evidence.

Report Organization

We have organized the report by Guiding Questions (GQs) and summarized relevant literature and Key Informant perspectives. GQ1, GQ2, and GQ4 reflect information found in published and unpublished literature, including opinion pieces and general materials. They also include the perspectives of our Key Informants. GQ3 is limited to a high-level evidence map of systematic reviews and empirical studies. Thus, GQ1 and GQ2 lay out the issues of relevance, while GQ3 identifies empirical literature on those issues. GQ4 then addresses challenges and opportunities related to implementation and dissemination.

The following GQs provide the structure for this Technical Brief.

GQ 1: Describe the intervention for resident safety practices in nursing home settings

GQ1a. What are the safety issues of particular concern in the nursing home setting?

GQ1b. Are there important differences in safety issues for short-stay versus long-stay residents?

GQ1c. Are there specific interventions that have improved patient safety in the hospital setting that could transfer to the nursing home setting, but have yet to be tested as such?

GQ 2: Describe the context in which the intervention is used for safety practices in nursing home settings

GQ2a. What characteristics and qualities of nursing homes and nursing home residents create unique settings for assessing safety and may affect choice of intervention and success rates? Considerations include:

- a. Staffing – type, education, numbers, turnover
- b. For-profit versus not-for-profit
- c. Bed size
- d. Particular vulnerability of the residents
- e. Resident mix, including short and long stay

GQ 3: Describe the current evidence of the intervention for safety practices in nursing home settings

GQ3a. What is the state of the current research based on the following criteria:

- a. Indication/resident inclusion criteria
- b. Type of intervention
- c. Study design/size
- d. Comparator

- e. Length of follow up
- g. Outcomes
- h. Sources of outcome data (i.e., facility self-report versus resident/family self-report versus objective, independent assessments)

GQ 4: Identify the important issues raised by the intervention for safety practices in nursing home settings

GQ4a. What is the uptake of evidence-based nursing home interventions beyond individual test sites? What are the most important barriers/facilitators to uptake of successful interventions?

GQ4b. What major areas for future research remain regarding resident safety in nursing homes?

GQ4c. In what ways is the field of long-term care changing such that resident safety interventions may need to adapt to a new environment, and what additional challenges do these changing conditions bring to increasing long-term care resident safety?

Scope

The issues addressed in this brief can be divided into two categories: safety events and factors that potentially contribute to safety events. We posit that in order to preserve the safety of nursing home residents, both must be addressed. Safety events (also known as adverse events) include: falls with injury, pressure ulcers, infection, including healthcare-associated infection (HAI), and medication errors and adverse drug events (ADE) (e.g., altered mental status, overuse of antipsychotic medications) including inappropriate medication use and polypharmacy. Potentially contributing factors include unintentional weight loss, including dehydration, decline in activities of daily living (ADL, typically defined as basic tasks of everyday life, including cooking, eating, bathing, dressing, toileting, transferring to different locations such as chair to bed or to a car) – functional independence, fecal and urinary incontinence, including constipation, depressive symptoms, moderate to severe pain, influenza vaccine, pneumococcal vaccine, physical restraints, and catheter left in bladder.^{24, 29, 38-40}

Methods

We used discussions with Key Informants and targeted searches of the published literature to collect relevant data. We used systematic reviews, narrative reviews, meta-analyses, and primary and secondary research studies to address GQ 1, 2, and 4.

For GQ3, we identified existing systematic reviews via literature searches described below and supplemented the studies presented in each selected review with a tabulation of new prospective comparative studies published since the most recent review's conduct.

Data Collection

Discussions with Key Informants

To identify key informants, we consulted with our content experts and searched the Web sites of relevant professional organizations and research and policy groups to identify stakeholders whose work or interests indicated a high likelihood of interest and expertise on the topic.

In consultation with the investigative team and AHRQ, we assembled a list of individuals representing perspectives including nursing home safety, hospital safety, quality of care, nursing home and assisted living administration, health services research, advocacy, policy, medication safety, and risk management. Seven of 20 invited individuals agreed to participate. We conducted three group discussions by telephone with Key Informants. We invited the Key Informants to share their experiences and make suggestions to address the proposed GQs. Before the call, we provided the participants with a copy of the protocol and GQs. We recorded and transcribed the call discussion and generated a summary that we distributed to call participants. We used the input from the Key Informants to provide additional context for issues related to resident safety in nursing homes and as a supplement to the empirical findings from the published literature. More details on the Key Informants and the discussions are in Appendix B.

Published Literature Search

We used a combination of controlled vocabulary terms and keywords to search the published literature for systematic reviews and studies that specifically evaluated interventions addressing the key safety areas identified above. We used two primary search strategies for GQ3:

1. We searched MEDLINE and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) using controlled and key terms for concepts including nursing home, long-term care, older adults, and the outcome areas (e.g., pressure ulcers, falls, infection) of interest, as well as related broad terms and descriptors. Our search strategies for this GQ focused specifically on the nursing home setting and the outcome areas of interest. We sought to identify recent existing systematic reviews and newly published literature. We searched these databases from 2005 to the present. We selected the 2005 start date to capture both literature published since the implementation of Nursing Home Compare (publicly accessible database of quality of care-related information that compiles data from Medicaid and Medicare certified nursing homes) in 1998 and the introduction of the CMS 5-Star quality rating in 2008.
2. We also updated the searches used in a sample of the systematic reviews we identified for GQ3 from the end search date of each selected review forward in order to identify newly published literature.

We present the literature search details in Appendix C.

Screening of Studies for GQ3

We screened the included literature for systematic reviews and publications that addressed one or more GQs. Two investigators independently screened the full text of each publication identified in the literature search using the criteria outlined in Table 4. Any discrepancies between investigators were resolved via discussion to reach consensus or via a senior investigator. We used a simple categorization scheme to code the reasons for exclusion from GQ3. We used EndNote® to record and track the disposition of references identified.

Table 4. Inclusion criteria for evaluation studies

Category	Criteria
Study population	Residents in nursing home facilities (short stay and long stay)
Publication languages	English only
Timeframe	2005 to the present
Admissible evidence	<p>Study design Systematic Reviews, Meta-analyses, Randomized controlled trials, Prospective intervention studies, including cohorts with comparison groups and pre-post studies</p> <p>Safety Outcomes and Potentially Contributing Factors Falls with injury Pressure ulcers Infection, including healthcare-associated infection, urinary tract infection, and antibiotic stewardship Medication errors and adverse drug events (e.g., delirium), including inappropriate medication use and polypharmacy Unintentional weight loss, including dehydration Decline in activities of daily living–functional independence Fecal and urinary incontinence, including constipation Depressive symptoms Overuse or inappropriate use of antipsychotic medications Moderate to severe pain Influenza vaccine Pneumococcal vaccine Physical restraints Catheter left in bladder</p>

Quality Assessment for GQ3

We used the Risk of Bias in Systematic Reviews (ROBIS) tool⁴¹ to assess the overall risk of bias of the included systematic reviews. The ROBIS tool is designed to assess relevance, potential for bias in the study eligibility criteria, identification and selection of studies, data collection and study appraisal, and synthesis and findings. One reviewer completed an assessment for each review after all reviewers initially completed scoring of the same set of test reviews in order to compare ratings and discuss any areas of discrepancy.

Data Organization and Presentation

We summarize information extracted from the published literature in the results and discussion sections of this report. We identified resident safety themes and contextual issues from expert input and the published literature and Key Informant discussions for GQ1 and GQ2. For GQ3, we summarize existing systematic reviews and original research published since the end date of the systematic reviews. We present summary tables and text to characterize the quantity and type of existing research for safety-related interventions in nursing homes (GQ3). In those tables, we describe the population, setting, search dates, study type and counts included in the systematic review, interventions, outcomes assessed, reported conclusions, and ROBIS score. In addition to describing the available systematic reviews, we catalogued the numbers and designs of newer studies that could potentially inform the assessment of interventions for each of the resident safety outcomes identified in Tables 5 and 6.

Peer Review

A draft of this Technical Brief will be posted to the AHRQ Web site for 4 weeks for public comments. During this time, the Scientific Resource Center (SRC) will distribute the draft report to individuals who agreed to serve as peer reviewers. The SRC collects the feedback from peer reviewers and forwards the compiled comments to report authors. We will review the comments and make appropriate changes to the final report. We will document the report revisions and provide a summary of responses to the individual comments received from public and peer reviewers in a disposition of comments table. The disposition of comments table will be available on the AHRQ Web site after publication of the final Technical Brief Report.

Findings

Following approval by AHRQ of the completed Disclosure of Interest forms for proposed Key Informants, we conducted discussions with seven Key Informants, representing the following fields of expertise: nursing home safety, hospital safety, quality of care, nursing home and assisted living administration, health services research, advocacy, policy, medication safety, and risk management.

GQ1a. What are the safety issues of particular concern in the nursing home setting?

The Challenge of Defining Resident Safety in Nursing Homes

The methods and processes of studying and applying safety in medicine have been largely driven by a need to improve safety for patients in hospitals. A problem for studying safety in the nursing home setting is that individuals residing in nursing homes are residents, and not patients. They may be residents in the facility for a number of years, so safety issues occur in the context of their normal life, not just during an acute hospitalization. The goals of nursing homes in caring for residents are not the same, for example, of a hospital, in which stabilization or cure are the focus of care. Instead, nursing homes try to balance providing maximum independence with ensuring safety of an increasingly frail population, who may be in residence for multiple years. The fact that the population includes people aging in their fulltime place of residence, rather than patients who present for short term or targeted care means that the commonly accepted, narrow foci of hospital-based safety measures are likely inadequate for nursing home care.

To frame this Technical Brief, we began with the definition of safety provided by AHRQ, which is a “*type of process or structure whose application reduces the probability of adverse events resulting from exposure to the care system across a range of diseases and procedures.*” We then referred to the Patient Safety Organization Privacy Protection Center (PSOPPC) Common Formats for Event Reporting on Nursing Home Safety Version 0.1 Beta (PSOPPC Common Formats) (Table 5). This set of outcomes, developed by AHRQ and in beta-testing, represents clear safety adverse events and is congruent with safety events that have been the focus of hospital care.

Table 5. Nursing home resident adverse events represented across reporting systems

Nursing Home Resident Safety Issue	AHRQ Common Formats for Event Reporting –Nursing Home Version 0.1 Beta ⁴²	MDS Quality Measure/ Indicator ³³	CMS Nursing Home Compare Quality Indicators –Long Stay ⁴³	CMS Nursing Home Compare Quality Indicators –Short Stay ⁴³	Top Litigated Issues in Nursing Homes ⁴⁴
Falls with injury	✓	✓	✓		✓
Pressure ulcers	✓	✓	✓	✓	✓
Infections, including healthcare-associated infection , urinary tract infection , and antibiotic stewardship	✓	✓	✓		
Medication errors and adverse drug events (e.g., delirium), including inappropriate medication use and polypharmacy	✓				

AHRQ=Agency for Healthcare Research and Quality; MDS=Minimum Data Set; CMS=Centers for Medicaid and Medicare Services

However, neither team experts nor Key Informants felt that this small set of indicators fully captured the safety issues for nursing home residents, although there is clear consensus that these measures are important and measurable outcomes in both hospital and nursing home care settings. To improve safety for nursing home residents, including addressing the adverse events above, potentially contributing factors to adverse events should also be targeted for improvement. Known factors that may contribute to safety events may include quality of care indicators, including those tracked in the MDS and Nursing Home Compare. By comparing these sources as well as common litigation targets, and consulting with key informants, we identified ten conditions that, if unchecked, have a high likelihood of resulting in a safety issue. For example, declines in ADLs could lead to an increased likelihood of falling, and a catheter left in too long could lead to infection. Our research team and key informants have proposed that to best address safety in the nursing home, the elements in both Tables 5 and 6 should be targets for intervention.

Table 6. Common contributing factors to safety events in nursing homes

Nursing Home Resident Safety Issue	AHRQ Common Formats for Event Reporting – Nursing Home Version 0.1 Beta ⁴²	MDS Quality Measure/ Indicator ³³	CMS Nursing Home Compare Quality Indicators –Long Stay ⁴³	CMS Nursing Home Compare Quality Indicators –Short Stay ⁴³	Top Litigated Issues in Nursing Homes ⁴⁴
Unintentional weight loss, including dehydration		✓	✓		✓
Decline in activities of daily living – functional independence		✓	✓		
Fecal and urinary incontinence, including constipation		✓	✓		
Depressive symptoms		✓	✓		

Nursing Home Resident Safety Issue	AHRQ Common Formats for Event Reporting – Nursing Home Version 0.1 Beta ⁴²	MDS Quality Measure/ Indicator ³³	CMS Nursing Home Compare Quality Indicators –Long Stay ⁴³	CMS Nursing Home Compare Quality Indicators –Short Stay ⁴³	Top Litigated Issues in Nursing Homes ⁴⁴
*Overuse or inappropriate use of antipsychotic medications		✓	✓	✓	
Moderate to severe pain		✓	✓	✓	
Influenza vaccine			✓	✓	
Pneumococcal vaccine			✓	✓	
Physical restraints			✓		
Catheter left in bladder			✓		

AHRQ=Agency for Healthcare Research and Quality; MDS=Minimum Data Set; CMS=Centers for Medicaid and Medicare Services

*We address overuse and inappropriate use of antipsychotic medications with medication errors in our summary.

Care Omissions

In addition, an area that underpins both safety and the related construct of quality is that of care omissions. Care omissions can be defined as (1) care documented in a resident’s medical record but not actually provided by staff; and, (2) the presence of a clinical condition not identified by staff and thus not reflected in the care plan and/or treatment decisions. Finally, prolonged delays in care delivery wherein care is provided but not in a timely manner may occur (e.g., delayed incontinence care or repositioning).

Care omissions may reflect a discrepancy between medical record documentation and direct observations of care delivery in the nursing home setting for incontinence care (e.g., toileting assistance and changing), feeding assistance during meals, nutritional supplement and snack delivery between meals, repositioning and mobility exercise.³⁷ Separate studies have shown that many clinical conditions go unrecognized and untreated by staff including depression, moderate to severe pain, inadequate food and fluid intake and unintentional weight loss.⁴⁵⁻⁴⁹ Similarly, other clinical conditions may be recognized by staff but not adequately addressed in resident care plans (e.g., incontinence and a toileting program). A recent Government Accounting Office (GAO) report indicated that fall risk, nutritional problems and incontinence are commonly experienced by nursing home residents but are not addressed in care plans.⁵⁰ Prolonged and/or excessive omissions of care may increase a resident’s risk for harm and subsequently be deemed as neglect/abuse in litigation (e.g., recurrent episodes of inadequate feeding assistance can lead to weight loss/dehydration).

During the development of this brief, the Office of the Inspector General (OIG) reported on adverse events in SNFs (i.e., short-stay) citing altered mental status, chronic constipation and excessive bleeding as events causing harm that were related to medication errors.³ None of these events is specifically noted in the sources we identified as a quality measure (Table 6). However, the report also noted that other adverse events causing harm to SNF patients (short-stay) may be broadly related to omissions of care, with the suggestion that care omissions are an underlying factor in many adverse events.

As an example, fluid imbalance/dehydration and exacerbation of a resident’s condition (e.g. heart failure) may both be a result of care omission but neither is routinely measured within the

current nursing home reporting system. We took note of these concerns, however, and included in GQ3 a review of the dehydration research literature because dehydration is often associated with unintentional weight loss and contributes to other adverse events (e.g., delirium, constipation) (Tables 5 and 6).

Several studies in addition to the recent OIG report have revealed that omissions of care are common in the nursing home setting.⁵¹⁻⁵⁴ It is important to note that residents who are cognitively impaired and/or physically dependent on staff for assistance are at higher risk for missed or delayed care occurrences and thus represent a target population (and the majority of residents) within the nursing home at high risk for adverse events.^{51, 52}

Person-Centered Care and Safety in Nursing Homes

Finally, as well as agreeing with our initial assessment of the key issues for resident safety in nursing homes and supporting the inclusion of quality of care measures that may contribute to safety issues, Key Informants added one additional concept, that of person-centered care as a way of supporting an environment less susceptible to safety lapses. A central tenet of person-centered care is staff compliance with residents' preferences and/or the ability of residents to make choices about aspects of their daily care and lives. A recent controlled trial demonstrated that direct care staff (e.g., nurse aides) could be trained to offer residents' choices more frequently in the context of daily care.⁵⁵ This study used a standardized observation protocol conducted by research personnel to document the change in related care processes. Notably, in baseline observations choice was rarely offered to residents during routine morning care (e.g., when to get out of bed, when to get dressed and what to wear, where/when to have breakfast), despite the fact that participating nursing homes had received in-service training related to person-centered care and staff self-reported that they recognized the value of choice. This finding underscores the importance of having an accurate measure of care process delivery in the nursing home setting. A separate RCT offered nutritionally at-risk residents a choice of snack and supplement items multiple times per day between meals. This study included independent assessments of food and fluid intake as well as body weight using standardized procedures. These studies report a positive impact of choice on resident outcomes including increased offers of choice and resident engagement in the care process (i.e., expressing preferences) as well as increased caloric intake.^{29, 56, 57}

An important challenge in providing person-centered care is the potential trade-off between resident quality of life and safety. For example, supporting a resident in being ambulatory increases the opportunity for falls to occur, and imposing dietary restrictions to control blood sugar or cholesterol may negatively affect food and fluid intake and body weight. Because nursing home residents live in a facility for a prolonged period of time, interventions to enhance quality of life are a component of preventing adverse events or other poor clinical outcomes. Quality of life and clinical care domains likely overlap for this population, as suggested by the National Quality Forum, which defined functional decline as a person-centered care measure.⁵⁸

Person-centered care approaches may have a potential impact on resident wellbeing and quality of life, and anecdotal evidence suggests that some approaches (e.g., Eden Alternative, Greenhouses) may produce both clinical and quality of life benefits, but the research literature is very limited (see GQ3).

GQ1b. Are there important differences in safety issues for short-stay versus long-stay residents?

Skilled nursing beds for short-term stays located within long-term care facilities represent the fastest growing segment of post-acute care, with 91 percent of nursing home beds dually certified for Medicare and Medicaid.⁹ Both nursing home and hospital populations experience falls and hospital readmissions thought to be preventable,^{3, 59} and both populations often require assistance with multiple activities of daily living (e.g., transfer out of bed, toileting, eating, walking), which increases their risk for care omissions and functional decline. There are, however, at least two related aspects of care that differentiate short- and long-stay residents: (1) management of the care transitions from acute care to post-acute care to home and (2) the delivery of rehabilitation services in preparation for discharge home.

Care Transitions and Safety

Transitions between care settings (acute to post-acute care to home) create vulnerability for multiple adverse outcomes. Older, hospitalized patients discharged to SNFs are more impaired than those discharged home, and this population may experience an exacerbation of their clinical conditions (e.g., unintentional weight loss, depression, pain) as a result of the hospitalization event. In recent studies, the transition from acute to post-acute care has been shown to be fragmented with incomplete clinical information necessary to provide care safely.^{60, 61} Recent data also suggest that at least some older adults are discharged from the hospital too soon with conditions that could be best treated by remaining in the hospital for a longer period of time⁶²; however, the scope and severity of this problem is unknown.

In short, the probability of adverse events during the transition from hospital to SNFs increases due to the stress of the hospitalization and transition process, a lack of timely, accurate clinical information necessary to care for this complex patient population in the nursing home setting, and the possibility that some patients may not be ready to leave the hospital. For example, adverse events related to medication errors in the SNF cited in the OIG report³ may be associated with multiple medications, particularly new medications, being prescribed for older patients discharged from the hospital to this care setting. In a recent study, hospitalized patients discharged to SNFs had an average of 13 medications on their hospital discharge list.⁶³ Thus, SNF providers face the challenge of starting complex new medication regimens with little knowledge of the patient or their medication history. These same safety issues exist for long-stay residents but to a lesser degree due to fewer care transitions and increased staff knowledge of the resident.

Rehabilitation Services and Safety

Another primary difference between short- and long-stay residents is the differential focus on rehabilitation services in preparation for discharge home. A major goal of skilled nursing care is to effectively rehabilitate residents to allow discharge to the least restrictive care environment possible which, in most cases, is a return to a community setting (e.g., own home residence or assisted living). Very few long-stay residents are expected to be discharged home or to another community setting. In contrast, 69 percent of SNF residents who were living at home prior to admission return home after their SNF stay.⁶⁴ Similar to the acute care to post-acute care transition, safety concerns relate to the transition from skilled nursing care to home and include the need for comprehensive care planning; effective, timely communication with outpatient

provider(s), scheduled followup visits within less than 30 days of discharge, persons' ability to safely manage their new medication regimen at home, and an accurate assessment of the need for other support services at home such as transportation, meals and home health).⁶⁵

Although short-stay residents are generally expected to return to community settings, one recent study reported that 33 percent of short-stay residents discharged home suffered an adverse medication-related event within 45 days of discharge, and only 28 percent of this group remained living at home 90 days after discharge.^{64,66} Ten percent experienced a hospital readmission within 30 days.⁶⁴ Based on these findings, new quality indicators are being developed by CMS and others for short-stay residents discharged home related to hospital readmission rates, with the rationale that this measure reflects the quality of the discharge process.

GQ1c. Are there specific safety interventions that have improved patient safety in the hospital setting that could transfer to the nursing home setting, but have yet to be tested as such?

The adverse events identified in Table 5 are also relevant to and have been studied in the acute hospital setting. Interventions for each have been developed and tested in the hospital setting. However, many safety issues in nursing homes are, as previously noted, directly related to the extended time period over which residents are in these facilities.

Although individual studies have been conducted and published on interventions to improve safety in hospitals, neither nationally representative data nor broad implementations of hospital-based interventions to address safety issues are easily available. Most of the literature describes single hospital implementations under tightly controlled conditions, with sparse data available on the potential for wider implementation, and even less for considering implementation across types of settings, such as to the nursing home. Such data would be required to correctly estimate the potential for these interventions to achieve target safety goals in nursing homes. A full review of hospital-based safety interventions is inappropriate for this Technical Brief, and without evidence of broader implementation or data on what is needed for implementation, it would be difficult to draw direct links to their potential for effect in nursing homes.

Nonetheless, we provide *selected examples* of interventions that have been studied in hospital settings as potential approaches below, while stressing that evidence is lacking specifically on generalizability of these interventions to the nursing home. We have no evidence of widespread adoption of these interventions, and thus implementation data that would be necessary to evaluate their potential for the nursing home setting are not presented. Furthermore, these studies do not focus on a population that matches that in the long-term care setting. We describe a selection of interventions here only to suggest approaches that might be studied further. This is followed by an assessment of national estimates that may be more representative.

Falls

Multifaceted and individualized falls prevention programs that have demonstrated effectiveness in limited hospital studies include a focused patient history and physical; educational programs for patients and staff; toileting programs; providing walking aids and making sure they are accessible and used sufficiently; and/or supervised exercise programs, especially those that combine balance, strength and power training. These appear to be most effective when designed and delivered by multidisciplinary teams.⁶⁷⁻⁷¹

Medication Errors

Medication review, either by pharmacists during the prescribing phase and/or by patients upon admission to the hospital and/or at discharge, has been associated with reduction in medication errors, preventable adverse drug events and adverse drug events (ADEs).⁷²⁻⁷⁸ Clinician engagement, multidisciplinary communication, and the review of medication lists and related risks for risk prevention and patient education, especially with older patients who are at risk due to higher acuity and/or actively take several medications, has also been shown to be effective and increase patient safety in the acute hospital setting.⁷⁹⁻⁸² It would seem that these types of interventions may be useful in the nursing home setting, particularly among short-stay residents who will be discharged home, and several systematic reviews (GQ3) have addressed medication review in the nursing home.

It is unclear whether technology intensive interventions, which are commonly seen in hospitals, could translate to the nursing home. Health information technology (HIT), such as computerized physician order entry (CPOE) and electronic health records (EHR) and databases that provide decision support (e.g., drug-drug interaction alerts, evidence-based guidelines, dosing alerts, etc.) have been shown to be effective and increase quality and medication safety as well as being more conducive and efficient for medication and chart reviews.⁸³⁻⁹⁰ We note hospital resources included an emphasis on bioinformatics and technological solutions may lessen the applicability of many of these interventions in the nursing home setting, or at least limit their generalizability unless nursing homes also have active and rich informatics systems for health records and management.

Pressure Ulcers

Most individually reported studies regarding pressure ulcers in hospitals assess treatment; however, quality indicators for nursing homes are related to the prevention of pressure ulcers. Therefore, a robust body of evidence on wound healing in hospitals provides limited guidance for long-term care beyond care practice guidelines to inform treatment of existing wounds.^{50, 91-94}

Infection

Catheter-associated UTIs (CAUTIs) may be the most avoidable type of hospital-associated infection (HAI).⁹⁵ A variety of strategies and guidelines for prevention and reduction in catheter-associated infections have been produced⁹⁶⁻¹⁰² as well as some AHRQ evidence reports/technology assessments on all healthcare-associated infections. These reports may provide some approaches for use in nursing homes.^{103, 104} Strategies for CAUTI prevention include proper techniques for urinary catheter insertion, which is reinforced by staff training, minimizing urinary catheter usage, using a closed urinary drainage system, avoiding catheter usage for incontinent patients, using external catheters instead of indwelling catheters, if possible, documentation of key information related to urinary catheters, and stop orders or reminders to remove such catheters. Some individual studies in hospital settings that have demonstrated positive findings also point to some potential practices. For example, antibiotic prophylaxis has been shown to effectively decrease the risk of UTIs in hospitalized patients undergoing short-term usage of catheters.¹⁰⁵ In addition to using aseptic catheter placement and maintenance, the use of silver-alloy catheters has also been recommended and has been shown to reduce CAUTIs, at least compared to the usage of uncoated catheters.¹⁰⁶

Policy Impact

Finally, in addition to individual studies, another and potentially more informative data source is national data available before and after large-scale payment reform. Specifically, in 2008, Medicare implemented a no-payment policy for specific conditions thought to reflect safety problems with hospital care including new pressure ulcers, falls, and catheter-related infections. Each of these is a significant safety issue of concern in the nursing home setting. If scalable interventions are available in the hospital setting, one could reasonably expect that rates should decrease as hospitals strove to implement services to prevent loss of income due to this policy. This should signal the true availability and potential scalability of the purported positive intervention effects above. In reality, data are mixed or negative on the degree to which improvements were seen after implementation of the no-payment policy in 2008.

Contradictory results reported by studies of pressure ulcer incidence may serve as a good example of issues related to data sources and collection. One retrospective, observational study reported significant reductions but acknowledged that the approach to data collection, which did not necessarily include all diagnosis codes in a given discharge, had high specificity for stage II and IV health care acquired pressure ulcers (HAPUs), but low sensitivity.¹⁰⁷ On the other hand, a quasi-experimental study of 1,381 hospitals participating in the National Database of Nursing Quality Indicators (NDNQI), which relied on trained nurses to assess HAPU prevalence, reported no effect of the payment policy on HAPU incidence. The NDNQI pressure ulcer indicator used in this study is, in fact, that endorsed by the National Quality Forum.¹⁰⁸

A second study using a non-claims database reported no improvement in injurious falls when measured before and after the introduction of the no payment policy. Data on hospital-acquired infections were similarly mixed with some studies reporting improvements and others reporting no change. National data¹⁰⁹ suggest substantial decreases since 2008 in many infections but not CAUTI, which have increased by about 6 percent.

Some recent data suggest that this trend is reversing, and the increase in CAUTI is contrary to clearly evidenced reductions in other infections, including central line associated bloodstream infections and hospital onset *Methicillin-resistant Staphylococcus Aureus* (MRSA) and *C. difficile* infections, none of which would be as relevant to the long-term care setting. In studies specifically intended to provide data before and after implementation of the policy, conclusions are mixed.^{108, 110-112} Indeed, some studies suggest that analyses based on hospital coding data, intended for billing purposes and reported for quality may not provide objective or optimal sources of information.

In general, hospitals have invested considerable resources in improving safety. Safety has improved in many areas that were not the focus of this review (e.g., surgical adverse events). However, in our brief review we could not ascertain that safety has improved for areas of most relevance to long-term care, with the possible exception of medication errors. Mixed evidence about hospital-based improvements in falls, pressure ulcers and catheter-related infections, even after a “no payment” policy was implemented, suggest that interventions to improve safety that have specific relevance to the nursing home population may not be consistently implemented in the hospital.

GQ2a. What characteristics and qualities of nursing homes and nursing home residents create unique settings for

assessing safety and may affect choice of intervention and success rates?

Both short and long-stay nursing home residents are vulnerable populations for multiple reasons including advanced age (70.4 percent aged 70 or older), medical complexity, the prevalence of ADL impairments (66.6 percent with three or more ADL impairments) and dementia (64.8 percent moderate to severe impairment) (Table 7). Nursing home residents need frequent, labor-intensive care (e.g., assistance getting in/out of bed, dressing, toileting, eating, walking) due to physical and cognitive deficits. Importantly, because nursing home residents remain in the facility for a prolonged period of time (average of 2.5 years), the care environment must have adequate staffing and organizational management over time to ensure that all aspects of care are provided 24-hours/day, seven days/week to all residents in need even as those needs change.

While staffing itself is not a safety outcome, it becomes clear that staffing challenges can be a contributor to adverse events. Staffing levels vary substantially, including nursing homes without adequate staffing to provide care consistent with federal regulations.⁹ Even higher staffed homes face challenges of a field with high turnover, the challenge of providing continuous training, and need to organize a complex array of daily tasks.

Table 7. Nursing home resident characteristics

Nursing Home Resident Characteristics*	Proportion Nationwide
Percent Female	67.2%
Percent White (non-Hispanic)	78.9%
Percent Age 75 or older	70.4%
Percent with 3 or more ADL Impairments	66.6%
Percent with Moderate to Severe Cognitive Impairment	64.8%

*Based on CMS data for 15, 683 nursing homes, Nursing Home Data Compendium 2012 Edition⁹

ADL=activities of daily living (e.g., transfer out of bed, dressing, toileting, eating, walking)

Staffing and Nursing Home Care Quality

Nursing home size and for-profit status are inversely associated with staffing levels.¹¹³⁻¹¹⁵ Importantly, readmissions, some MDS-derived quality indicators, and survey deficiencies are also more common in larger and for-profit nursing homes.^{9, 116} Although the overall staffing level may be the mediating variable associated with these poor outcomes, and evidence suggests that many care processes are provided more consistently in higher staffed homes, the picture is more complex than simply that of adequate numbers.¹¹⁷ Even in higher staffed homes, problems occur and may be associated with the challenges described above in turnover, training, and educational level of staff.

Type of Staff

In contrast to hospitals and hospital care, nursing homes rely on many non-licensed personnel (e.g., nurse aides) who are responsible for a great deal of labor-intensive and non-clinical ADL care. Nurse aides must be certified but do not have the level of education required of nurses, and typically do not hold a professional license. In contrast, personnel at the Licensed Practical Nurse/Licensed Vocational Nurse (LPN/LVN) and Registered Nurse (RN) level serve in a supervisory role in nursing homes and are responsible for the more clinical aspects of care (e.g., wound treatments, medication delivery, assessments). Research suggests that a higher number of RNs is associated with improvements in clinical outcomes (e.g., pressure ulcers, weight loss).¹¹⁸

The heavy reliance on non-licensed personnel presents significant challenges to management and organization of nursing home care, in a situation in which staff members need to be well-organized and well-managed to care for very complex resident needs. This suggests a significant need to focus on management training for nurses and others in supervisory roles that may differ from that in the hospital setting.¹¹⁹

Number of Staff

A small and mixed body of research has explicitly explored the association of staffing levels and quality of care issues that may contribute to safety. In general, systematic and narrative reviews have reported mixed evidence related to the effects of staffing levels on safety outcomes, typically with positive effects of higher staffing levels on pressure ulcers. Studies overall were considered methodologically flawed in the reviews that commented on study quality, and reviews generally commented on variation in methods to measure staffing. One systematic review of 87 research articles and reports from 1975-2003 found that high total staffing levels, especially licensed staff (RNs and LPNs/LVNs), were associated with higher quality outcomes, particularly related to functional decline, pressure ulcers, and unintentional weight loss.¹¹⁸ A narrative review of 59 studies on nursing home staffing from 1991-2006 found that 40 percent of the care quality indicators had significant positive associations with staffing, and 5 percent were negative.³⁵

A recent systematic review of 50 research studies of staffing and quality from 1987-2008 found a positive relationship between staffing and quality in some studies while other studies had mixed results.¹²⁰ Another review of 20 longitudinal nursing home research studies found that more staff were associated with fewer pressure ulcers but other outcomes had mixed findings.¹²¹ Finally, a 2015 review (not a systematic review) included 67 articles on RN staffing published from 2008-2014. According to the review authors, some studies reported that higher RN staffing levels were associated with fewer pressure ulcers, lower physical restraint use, reduced hospitalizations, fewer deficiency citations, decreased mortality, and decreased urinary tract infections.¹²² The data in this review are not presented in such a way that the reader can reliably know which studies reported positive outcomes and which did not.

In practice, the Institute of Medicine recommends that overall staffing levels should be set at 4.1 total hours per resident day (HPRD) to include a minimum 2.8 nurse aide HPRD, 0.75 RN HPRD, and 0.55 LPN/LVN HPRD. Nationally, the overall average reported by facilities for total HPRD is 4.1, while the average for nurse aides is 2.5 (Table 3). In addition, an acuity based approach is available but not widely used – namely the Resource Utilization Groups (RUGs) designed for short-stay residents – comparing RUGs expected staffing levels to Nursing Home Compare demonstrates that 59 percent of nursing homes fall below recommended levels under this system.¹²³ Indeed, CMS recently proposed at the White House Conference on Aging (July 13, 2015) that resident-acuity based staffing models be a revision to long-term care standards to ensure the safety and health requirements for nursing home residents.¹²⁴

GQ3. Current evidence of interventions for improving safety practices and contributors to safety issues in nursing home settings

Overview of All Systematic Reviews

Studies of interventions intended to improve safety outcomes among the nursing home population may be targeted interventions to change specific outcomes, or more general or multifaceted interventions with multiple outcomes. In this section, we provide an overview of literature on both the safety outcomes and potential contributing factors noted in Tables 5 and 6. The 62 reviews meeting our inclusion criteria may have addressed multiple outcomes but typically focused on a primary outcome such as falls prevention. For the purposes of organizing GQ3 results, we have summarized reviews specifically addressing a given outcome area in that specific section, although we recognize that there may be other optimal organizational approaches. The final section includes summaries of reviews that were more generally focused – for example on staffing models – and that include multiple outcomes.

Some reviews also broadly targeted older adults and may only include a small number of studies that were conducted in nursing homes, but also include hospital-based or community based settings. We elected to include these reviews in the Technical Brief to provide a comprehensive picture of the literature potentially relevant to older adults rather than eliminating reviews with mixed care settings. All reviews included nursing home studies. Whenever possible, we focused on data from nursing home or long-term care settings. We also provide an estimate of new studies published since the ending search date of the reviews addressed in each section and identified in our screening of the primary literature. The purpose of this estimate is to begin to identify areas of research that might warrant an updated or new review.

The following reviews include studies evaluating adverse events in the nursing home setting (Table 5).

Interventions to Prevent Falls

Key Points

- Fourteen reviews (five high, one unclear, and eight low risk of bias) focused on falls prevention. The quality of included studies varied across reviews, but many were considered methodologically flawed. Outcomes assessed varied across studies and included number or rate of falls and fallers, recurrent fallers, risk of falls, risk of fractures, and numbers of fractures. Few studies evaluated adverse effects of interventions.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 16 RCTs, three prospective intervention studies, including cohorts with comparison groups, and two pre-post studies with comparison groups.

Overview of Reviews

A wide range of interventions may be associated with the outcome of falls prevention, including those interventions aimed at toileting, preventing delirium, ensuring appropriate medication use and use of physical restraints. Thus, the reviews included here (Table 8), which

focus specifically on falls prevention represent a subset of potential intervention studies on this topic. To provide greater detail on the types of interventions evaluated, Tables 9 and 10 outline the outcomes and intervention components addressed in studies included in the 14 reviews of falls prevention approaches.^{24, 69, 125-136}

Several reviews assessed multiple interventions or multimodal approaches.^{24, 69, 125, 128, 130, 133, 136} Among those with low risk of bias, the most recent was published in 2015 and included 13 RCTs published through 2013.¹²⁵ Interventions assessed in the review included staff training, written materials, informatics tools for appropriate medication use, vitamin D supplementation, exercise programs, modifications to the environment, management of urinary incontinence and nutrition therapy. Overall, 22,915 participants were included across all 13 individual studies in the review. Outcomes included numbers of falls, numbers of fallers and numbers of recurrent fallers, with positive outcomes found in reducing recurrent fallers but no significant effects on other outcomes. A 2012 Cochrane review included 60 RCTs, also with a diverse set of interventions that were implemented in nursing homes and in hospitals.²⁴ This review also examined number of falls and fallers, as well as fractures, complications and economic outcomes. A 2010 review addressing multiple interventions including Vitamin D, exercise, pharmacologic therapies, and hip protectors included 20 RCTs, most assessing Vitamin D or hip protectors.¹³³ The review reported significant reductions in hip fracture risk associated with Vitamin D and conflicting evidence for hip protectors. Reductions in falls were associated with exercise, but neither staff education or risk assessment was associated with fall reductions. Studies had limited quality overall. A 2007 review of 43 studies (approximately 27 in nursing homes) reported limited evidence for any intervention in the nursing home setting except Vitamin D supplementation and hip protectors to prevent fractures.⁶⁹

Other reviews specifically examined a single category of intervention such as exercise,^{126, 135} environmental modification,¹²⁹ hip protectors,^{131, 132, 134} and vitamin D supplementation.¹²⁷

Table 8. Overview of systematic reviews for falls

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Characteristics and effectiveness of fall prevention programs in nursing homes: a systematic review and meta-analysis of randomized controlled trials (Vlaeyen et al., 2015) ¹²⁵ ROBIS: Low	Population: Nursing home residents Setting: Nursing home Search dates: Up to September 2013 Included study type/counts: 13 RCTs (2 individual RCTs; 12 cluster RCTs)	Single intervention: 1. Staff training 2. Staff Knowledge 3. Medication Informatics tool to analyze and review medication use 4. Assessment of medication needs 5. Vitamin D supplementation 6. Exercise 7.Environmental: Furnishings and Adaptations Body-worn aids; protection Aids for personal mobility 8.Other: Management of urinary incontinence; Fluid or nutrition	Number of falls, fallers and recurrent fallers	Fall prevention programs did not reduce the number of falls or fallers, but significantly reduced the number of recurrent fallers by 21%.

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
		therapy; Advice on correction of orthostatic hypotension; Optician referral Multiple interventions: Incontinence care and a low-intensity, functionally oriented exercise program Multifactorial intervention:		
Hip protectors for preventing hip fractures in older people (Santesso et al., 2014) ¹³⁴ ROBIS: Low	Population: older age (>65) Setting: Living in community or residential care Search Dates: Up to 2012 Included study type/counts: 19 RCTs and non-randomized comparative trials	Hip protector	Risk of hip or pelvic fracture; Rate of fracture; Rate of falls	For nursing home resident hip protectors were associated with a small reduction in hip fracture risk and a slight increase in pelvic fracture risk. There was no significant effect on other fracture or falls. The strength of evidence was moderate quality.
Interventions for preventing falls in older people in care facilities and hospitals (Cameron et al., 2012) ²⁴ ROBIS: Low	Population: Older patients Setting: Long-term care and hospitals Search dates: 1946 to August 2012 Included study type/counts: 60 RCTs	1. Exercises 2. Physiotherapy 3. Medication review by a pharmacist 4. Vitamin D supplementation 5. Environment/assistive technology 6. Social environment (staff training and service model change) 7. Knowledge	Rate of falls; Number of fallers; Number of participants sustaining fall-related fractures; Complications of the interventions; Economic outcomes	Vitamin D supplements reduced the rate of falls. Exercise interventions showed inconsistent results. The evidence for multifactorial interventions was also inconclusive.
Interventions designed to prevent healthcare bed-related injuries in patients (Anderson et al., 2011) ¹²⁹ ROBIS: Low	Population: Patients in residential healthcare Setting: Residential healthcare setting Search dates: Up to December 2010 Included study type/counts: 2 RCTs	1. Low height beds 2. Bed exit alarms	Frequency of patient injuries from their beds; Frequency of patient falls out of bed Frequency of patient injuries due to falls out of bed Frequency of patient injuries due to the intervention; Frequency of all falls Frequency of patient injuries due to all falls	No effectiveness of low height beds or bed alarms in reducing injuries or falls from beds. Evidence was limited.
Exercise for improving balance in	Population: Adults age 60 or older	Exercise programs, including gait and	Balance	Limited evidence that exercise

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>older people (Howe et al., 2011)¹³⁵</p> <p>ROBIS: Low</p>	<p>Setting: Community or institutional settings</p> <p>Search dates: Up to 2011</p> <p>Included study type/counts: 94 RCTs</p>	<p>balance, strengthening exercises, 3 dimensional exercise programs, general physical activity, computerized balance training, vibration platform</p>		<p>programs are effective in improving balance outcomes.</p>
<p>A scoping review of strategies for the prevention of hip fracture in elderly nursing home residents (Sawka et al.,2010)¹³³</p> <p>ROBIS: Low</p>	<p>Population: Elderly (≥ 65 years) nursing home residents</p> <p>Setting: Long-term care setting</p> <p>Search dates: 1975 to 2009)</p> <p>Included study type/counts: 20 RCTs</p>	<p>1. Vitamin D or calcium 2. Non-hormonal pharmacologic therapies for osteoporosis 3. Hormonal therapies (or hormone analogues) 4. Oral or parenteral alternative medicines 5. Exercise, behavioral interventions, physiotherapy, education, or multimodal interventions 6. Hip protectors</p>	<p>Number of hip fractures; Fracture risk</p>	<p>Vitamin D supplementation reduced hip fracture risk. More research is needed on other interventions including pharmacologic treatment, exercise, multi-modal strategies and hip protectors.</p>
<p>Hip protectors decrease hip fracture risk in elderly nursing home residents: a Bayesian meta-analysis (Sawka et al., 2007)¹³¹</p> <p>ROBIS: Low</p>	<p>Population: Elderly (≥ 65 years) nursing home residents</p> <p>Setting: Nursing home</p> <p>Search dates: 1996 to 2006</p> <p>Included study type/counts: 4 RCTs (including 3 cluster RCTs)</p>	<p>Hip protectors</p>	<p>Hip fractures</p>	<p>Hip protectors decreased the risk of hip fractures.</p>
<p>Do hip protectors decrease the risk of hip fracture in institutional and community-dwelling elderly? A systematic review and meta-analysis of randomized controlled trials (Sawka et al, 2005)¹³²</p>	<p>Population: Elderly (≥ 50 years)</p> <p>Setting: Institutional and community-dwelling</p> <p>Search dates: 1998 to 2004</p> <p>Included study type/counts: 7 RCTs</p>	<p>Hip protectors Educational co-interventions</p>	<p>Hip fractures</p>	<p>More research needed to assess effectiveness of hip protectors in reducing hip fractures in nursing home residents.</p>

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS: Low				
Exercise for falls and fracture prevention in long term care facilities: a systematic review and meta-analysis (Silva et al., 2013) ¹²⁶ ROBIS: High	Population: Older adults Setting: Long-term care Search dates: January 1974 to June 2012 Included study type/counts: RCTs = 12	Physical exercise regime: Balance and resistance training exercises	Falls and fracture prevention	Exercise programs work for fall prevention but were not effective in preventing fractures.
Falls prevention for the elderly (Balzer et al., 2012) ¹²⁸ ROBIS: High	Population: 60 years or older Setting: Home or long-term care settings Search dates: January 2003 to January 2010 Included study type/counts: 184 studies	Exercise, instruments and assessments for fall risk, assessment and correction of visual acuity, surgical interventions, educational, hip protectors, gait stabilizing footwear, Vitamin D, dietary supplements, multiple and multifactorial interventions	Prevention of falls and fall-related injuries	Lack of evidence to support fall prevention recommendations.
Effectiveness of intervention programs in preventing falls: a systematic review of recent 10 years and meta-analysis (Choi et al., 2012) ¹³⁶ ROBIS: High	Population: Older adults Setting: Nursing home and community settings Search Dates: 2000 to 2009 Included study type/counts: 17 RCTs	Fall prevention	Number of falls and fall rate	Fall-prevention programs effective in reducing fall rates by 14%. There was a 54% fall reduction in nursing homes (3 studies)
Association Between Vitamin D Dosing Regimen and Fall Prevention in Long-term Care Seniors (Chua et al., 2011) ¹²⁷ ROBIS: High	Population: 75 years or older Setting: Long-term care settings Search dates: 2000 to 2010 Included study type/counts: 4 RCTs	Vitamin D	Rate of falls and number of fallers	Vitamin D supplementation reduced the rate of falls but not the number of fallers.
Effectiveness of multifaceted fall-prevention programs for the elderly in residential care	Population: 60 and older Setting: Residential care	Multifaceted fall programs (included more than 1 intervention) with at least 6 month follow-	Number of residents sustaining a fall; Number of falls; Number of injuries resulting from falls;	Multifaceted programs have shown some evidence of efficacy (three studies report

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
(Cusimano et al., 2008) ¹³⁰ ROBIS: High	Search dates: Up to 2007 Included study type/ counts: 5 RCTs	up	Number of recurrent fallers	significant reductions in number of recurrent fallers, two reported significant reductions in number of falls)
Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses (Oliver et al., 2007) ⁶⁹ ROBIS: Unclear	Population: Nursing home patients with cognitive impairment and depression Setting: Nursing home Search dates: Up to January 2005 Included study type/ counts: 16 RCTs; 12 cluster RCTs; 2 prospective; 2 retrospective observational cohort; 2 prospective observational cohort; 1 prospective case-control study; 1 quasi-experimental	Single interventions: 1.Hip protectors 2.Removal of physical restraint 3.Fall alarm devices 4.Exercise 5.Environment 6.Calcium and Vitamin D 7.Medication review	Number or rate of falls; Number or rate of fallers; Number or rate of fractures	Hip protectors in care homes reduced hip fractures. There was insufficient evidence to evaluate other single or multifaceted interventions.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial

The most common outcomes studied in these systematic reviews were the number and rate of fractures and the number and frequency of falls (Table 9).

Table 9. Outcomes addressed in systematic reviews for falls

Outcomes Assessed	Risk of fracture or fall	Falls and fracture prevention	Frequency of patient injuries due to all falls/ falls out of bed /from their beds	Number/ rate /frequency of falls/ fallers; change in percentage of falls; incidence of falls	Number/ rate of fractures/hip fractures	Number of recurrent fallers	Complications/Harms of the falls interventions	Economic outcomes
Vlaeyen et al., 2015 ¹²⁵				✓		✓		
Santesso et al, 2014 ¹³⁴	✓			✓	✓			
Cameron et al., 2012 ^{24*}				✓	✓		✓	✓
Anderson et al., 2011 ¹²⁹			✓	✓			✓	
Howe et al., 2011 ^{135**}								✓
Sawka et al., 2010 ¹³³					✓			
Sawka et al., 2007 ¹³¹					✓			

Outcomes Assessed	Risk of fracture or fall	Falls and fracture prevention	Frequency of patient injuries due to all falls/falls out of bed /from their beds	Number/ rate /frequency of falls/ fallers; change in percentage of falls; incidence of falls	Number/ rate of fractures/hip fractures	Number of recurrent fallers	Complications/Harms of the falls interventions	Economic outcomes
Sawka et al., 2005 ¹³²					✓			
Silva et al, 2013 ¹²⁶		✓						
Balzer et al, 2012 ^{128*}	✓	✓	✓		✓		✓	✓
Chua et al., 2011 ¹²⁷				✓				
Cusimano et al., 2008 ¹³⁰			✓	✓		✓		
Oliver et al., 2007 ⁶⁹				✓	✓			

*Balzer et al., 2012¹²⁸ also assesses legal, ethical, and social aspects of interventions

**Howe et al., 2011¹³⁵ also assessed measures of balance and walking speed.

Table 10 outlines the most frequently evaluated interventions included in unique studies across reviews (individual studies were typically included in multiple reviews). Overall, reviews addressing falls prevention included 80 unique studies conducted in nursing homes (reviews also included studies conducted in other settings). Interventions evaluated in studies typically included multiple components, and we classified components of interventions broadly. We recognize that some elements could be categorized in multiple ways, but the table is intended to present a broad estimate of the approaches addressed in studies.

Table 10. Most commonly reported components of falls prevention intervention studies

Intervention Component	Estimated Number of Studies Including Component
Exercise	32
Hip protectors/protective aids	20
Staff training/education	18
Falls/safety risk assessment	10
Vitamin D supplementation	10
Environmental modification, including physical alerts to identify fallers (e.g., wristband, etc.)	7
Guidelines/treatment recommendations	6
Medication review	6

Pressure Ulcers

Key Points

- Eight reviews (3 low risk of bias and 5 high) included largely poor quality studies measuring heterogeneous healing-related outcomes.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 16 RCTs, three prospective intervention studies, including cohorts with comparison groups, and two pre-post studies with comparison groups.

Overview of Reviews

Eight systematic reviews specifically focused on preventing and treating pressure ulcers (Table 11).^{93, 137-143} One low risk of bias review focused on repositioning and included only 3 RCTs, with a final search date in 2013.¹³⁷ The review found no strong evidence for the benefit of a 30 degree tilt compared to 90 degrees, and no good evidence of a specific effect of repositioning frequency. Two low risk of bias reviews conducted by AHRQ EPCs addressed multiple interventions for pressure ulcer prevention¹⁴² and treatment.¹⁴¹ The prevention-focused review included roughly 20 comparative studies in nursing home or long-term care settings and reported moderate quality evidence for a lower risk of ulcers with advanced static support mattresses or overlays compared with standard mattresses in high risk populations. The review noted limited evidence to support the use of other support surfaces (e.g., low air loss mattresses) and insufficient evidence for interventions such as repositioning and cleansers in preventing pressure ulcers. The treatment-focused review included approximately 45 randomized or observational studies in nursing home or long-term care facilities and reported moderate evidence for the effect of air-fluidized beds, nutritional supplements, radiant heat dressings, and electrical stimulation on wound improvement compared with placebo or other interventions. The review found limited evidence for effects of alternating pressure mattresses, hydrocolloid dressings, light therapy, and platelet-derived growth factor on improved healing.

Two reviews of multiple interventions (both high risk of bias) reported little evidence for most modalities studied.^{140, 143} Three other reviews with high risk of bias largely focused on education and process of care and reported mixed results from studies that were not of high quality.

Table 11. Overview of systematic reviews for pressure ulcers

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Repositioning for pressure ulcer prevention in adults (Gillespie et al., 2014)¹³⁷ ROBIS: Low	Population: Older patients Setting: Acute & long-term care Search dates: 1948 to September 2013 Included study type/counts: 1 RCT; 2 cluster RCTs	1. 30 degree vs. 90 degree tilt positions 2. Two-hourly and 3-hourly repositioning on standard hospital mattresses and 4 hourly and 6 hourly repositioning on viscoelastic foam mattresses	Proportion of participants with a new pressure ulcer of any stage, grade, or category; HRQoL; Procedural pain; Patient satisfaction; Cost of ulcer prevention and cost per event avoided	No benefits associated with mattress tilt angles or increased repositioning frequency. Limited and low quality evidence.
Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness (Chou et al., 2013)¹⁴² ROBIS: Low	Population: Adults Setting: Any Search Dates: Up to 2012 Included study type/counts: 120 studies	Risk assessment scales to identify high risk and prevention interventions to decrease incidence or severity	Pressure ulcers	Advanced static support surfaces more effective in ulcer prevention compared to standard mattresses in higher risk populations
Pressure Ulcer Treatment Strategies: Comparative	Population: Adults 18 and older treated for existing pressure ulcers	Surface supports, nutrition supplementation, wound dressings,	Effectiveness and safety of pressure ulcer treatment strategies	Moderate strength evidence that air-fluidized beds, protein containing

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Effectiveness (Saha et al., 2013) ¹⁴¹ ROBIS: Low	Setting: Any Search Dates: 1985 to 2012 Included study type/counts: 174 studies	topical therapies, biologic agents, surgical repair		nutritional supplements, radiant heat dressings, and electrical stimulation associated with wound improvement. Limited evidence regarding best treatment for pressure ulcers.
Preventing in-facility pressure ulcers as a patient safety strategy: a systematic review (Sullivan et al., 2013) ¹³⁸ ROBIS: High	Population: Hospital patients (acute & long-term care) Setting: Hospital (acute and long-term) Search dates: 2000 to 2012 Included study type/counts: 26 studies (including 3 RCTs)	multicomponent initiatives (evidence-based clinical decision tools combined with training and education)	Improvement in pressure ulcer rates; Process of care quality measures	Multicomponent interventions improved care and reduced rates of pressure ulcers.
Comprehensive programs for preventing pressure ulcers: a review of the literature (Niederhauser et al., 2012) ¹³⁹ ROBIS: High	Population: Patients in acute care and long-term care Setting: Acute care and long-term care Search dates: January 1995 to December 2010 Included study type/counts: 24 case series (1 longitudinal group pretest-posttest design)	Multifaceted, multidisciplinary interventions (Pressure Ulcer prevention best practices, staff education, clinical monitoring and evaluation, skin care champions, other campaign elements, and strategies to ensure sustainability)	Pressure Ulcer prevalence or incidence rates; Care process measures	Multi-disciplinary, bundled approaches can reduce pressure ulcer prevalence or incidence rates.
Pressure ulcer prevention: an evidence-based analysis (Ontario, 2009) ⁹³ ROBIS: High	Population: 60 to 80 year olds Setting: Long-term care homes Search dates: Up to 2003 Included study type/counts: 2 RCTs; 3 Non-RCTs	Risk assessment Distribution devices Nutritional supplements Repositioning Incontinence management	Incidence of pressure ulcers	Moderate evidence of effectiveness of alternative foam mattress compared to standard hospital foam mattress for preventing PU. Lack of evidence to support most other preventive interventions.
Pressure ulcers (Cullum et al., 2008) ¹⁴⁰ ROBIS: High	Population: NR Setting: NR Search Dates: Up to 2007	Prevent formation, heal existing ulcer, improve quality of life	Incidence and severity of pressure ulcers; Time to heal; Adverse effects of treatment	Alternative foam mattresses reduce incidence of pressure ulcers. Air-fluidized supports and hydrocolloid

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
	Included study type/counts: 60 studies including systematic reviews, RCTs and observational studies			dressings may improve healing
Treatment of pressure ulcers: a systematic review (Reddy et al., 2008) ¹⁴³ ROBIS: High	Population: Adults Setting: Any Search Dates: Up to 2008 Included study type/counts: 103 RCTs	Treatments for pressure ulcers	Pressure ulcers	No evidence favored one support system over another. One study found protein supplementation improved healing. No benefits shown in 21 RCTs evaluating adjunctive therapies

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; NR=Not reported

Infections, Including Healthcare-associated Infection, Urinary Tract Infection, and Antibiotic Stewardship

Key Points

- Three systematic reviews (1 low and 2 high risk of bias) focused on infection prevention (one on MRSA prevention, one on oral hygiene, and one on various non-pharmacologic infection prevention measures). Reviews typically reported that studies had limited methodologic rigor.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified seven RCTs and one prospective intervention study, including cohorts with comparison groups.

Overview of Reviews

We separate the three reviews addressing infection prevention¹⁴⁴⁻¹⁴⁶ from the set of reviews focusing on increasing vaccinations below (Table 12). In one Cochrane review of methods to prevent transmission of MRSA in nursing homes, only one study, a cluster randomized trial of 32 sites (16 matched pairs), was included. The intervention included providing baseline data and infection control education to the staff as well as infection control audits and was not associated with significant changes in infection rates.¹⁴⁴ Another review evaluated evidence for infection prevention interventions from 24 studies (16 RCTs) and provided little synthesis across studies.¹⁴⁶ Studies addressed therapeutic or educational interventions including oral hygiene education, antifungal medications, hand sanitizer, vitamin E or other supplements, chlorhexidine bathing, and pneumococcal vaccine across multiple infection sites. The final systematic review addressed the preventive effect of oral hygiene on pneumonia and respiratory tract infection (RTI) in the elderly in nursing homes and hospitals. This review included only RCTs and was published in 2009.

Table 12. Overview of systematic reviews for infections, including healthcare-associated infection, urinary tract infection, and antibiotic stewardship

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>Infection control strategies for preventing the transmission of methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) in nursing homes for older people (Hughes, 2013)¹⁴⁴</p> <p>ROBIS: Low</p>	<p>Population: Nursing home residents</p> <p>Setting: Nursing home</p> <p>Search dates: Up to 2013</p> <p>Included study type/counts: 1 RCT (cluster in 32 homes)</p>	Infection prevention and control	MRSA prevalence	No change in MRSA prevalence between intervention and control sites reported in a single study.
<p>Infection prevention in long-term care: a systematic review of randomized and nonrandomized trials (Uchida et al., 2013)¹⁴⁶</p> <p>ROBIS: High</p>	<p>Population: Elderly (≥ 65)</p> <p>Setting: Nursing homes</p> <p>Search Dates: 2001 to 2011</p> <p>Included study type/counts: 24 studies (16 RCTs; 8 non randomized comparative studies)</p>	Non pharmacological infection-prevention interventions	Infection rates and reduction in risk factors related to infections	Primary purpose for most RCTs was to reduce pneumonia. 13 out of 24 (54%) reported statistically significant results for at least one outcome. No standardized definition to examine infection rates
<p>A systematic review of the preventive effect of oral hygiene on pneumonia and respiratory tract infection in elderly people in hospitals and nursing homes: effect estimates and methodological quality of randomized controlled trials (Sjogren, 2008)¹⁴⁵</p> <p>ROBIS: High</p>	<p>Population: Elderly population</p> <p>Setting: Hospitals and nursing homes</p> <p>Search dates: 1996 to 2006</p> <p>Included study type/counts: 5 RCTs; 10 other including: case-control, cross sectional, retrospective longitudinal</p>	Oral hygiene	Frequency of pneumonia or lower respiratory tract infection	RCTs showed positive preventive effects of oral hygiene on pneumonia and RTI

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; MRSA=Methicillin-resistant *Staphylococcus aureus*; RTI=Respiratory tract infection

Medication Errors and Adverse Drug Events (e.g., delirium), Including Inappropriate Medication Use and Polypharmacy

Key Points

- Across ten reviews (7 low, 1 unclear, and 2 high risk of bias), studies were typically considered to have moderate to high risk of bias.

- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified two RCTs and four prospective intervention studies, including cohorts with comparison groups.

Overview of Reviews

Ten systematic reviews focused on identifying interventions to prevent medication errors and adverse drug events through approaches to improve prescribing and reduce inappropriate use of drugs (Table 13). Five reviews focused broadly on optimizing prescribing or medication safety.^{90, 147-151} One addressed antibiotic prescribing specifically,¹⁵² another evaluated medication reconciliation in care transitions,¹⁴⁷ and a third evaluated specific effects of medication reviews on mortality and hospitalization.¹⁵³ To categorize approaches addressed in studies in these reviews further, Table 14 outlines frequently studied components of the interventions.

One Cochrane review on polypharmacy included 12 studies with 22,438 participants; three studies were conducted in the nursing home setting and included 8,320 participants.⁹⁰ Most studies in the review evaluated multicomponent interventions (including education and medication review components) intended to promote appropriate medication use. Another review focused on medication reconciliation during transition to and from long-term care.¹⁴⁷ One review of third party medication reviews in nursing home residents to reduce mortality and hospitalization included seven RCTs and five non-RCTs.¹⁵³ Another review focused specifically on clinical decision support systems to improve medication safety in long-term care settings¹⁵¹ and included seven studies (5 RCTs).¹⁵¹ Studies generally reported positive effects on appropriate prescribing decision-making and mixed results related to improvements in potential adverse drug reactions.

One Cochrane review identified two trials of 3636 participants that focused on non-pharmacologic delirium prevention approaches. Both studies suffered from lack of blinding and the manuscripts had inadequate reporting. Of the two studies, one was a very small hydration-based intervention that found no effect, and the other was a large cluster-RCT of a computer system to identify medications that could trigger delirium and included pharmacist medication review. This study reported a large reduction in delirium in nursing home staff-reported assessments.¹⁵⁴

Table 13. Overview of systematic reviews for medication errors and adverse drug events

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Interventions for preventing delirium in older people in institutional long-term care (Clegg et al., 2014) ¹⁵⁴ ROBIS: Low	Population: Older patients Setting: Long-term care Search dates: Up to April 2013 Included study type/counts: 2 cluster RCTs	1. Hydration-based intervention 2. Computer program which searched prescriptions for medications that might increase the chance of developing delirium	Prevalence, incidence, and severity of delirium	Very limited evidence (only 2 studies) Computerized system to identify medications and trigger pharmacist review reported a reduction in delirium incidence in a single study. A small hydration study was negative.
Interventions to improve the appropriate use of	Population: Adults > age 65 with more than one long-term	Interventions to improve polypharmacy,	Primary Outcomes: Appropriateness of prescribed	Interventions helped reduce inappropriate prescribing, but no

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
polypharmacy for older people (Patterson et al., 2014) ⁹⁰ ROBIS: Low	medical condition Setting: Any Search dates: Up to Nov 2013 Included study type/counts: 12 RCTs	including professional/educational, organizational, financial and regulatory	medications; Prevalence of appropriate medication; Hospital admissions Secondary outcomes: Medication-related problems (adverse drug reactions, drug-drug interactions, medication errors); Medication adherence; Quality of life	evidence of corresponding clinical improvement
Medication reviews for nursing home residents to reduce mortality and hospitalization: systematic review and meta-analysis (Wallerstedt et al., 2014) ¹⁵³ ROBIS: Low	Population: Nursing home residents Setting: Nursing home Search dates: January 1990 to June 2012 Included study type/counts: 7 RCTs; 5 non-RCTs	Medication reviews	Mortality; Hospitalization	Medication reviews for nursing home residents were not effective in decreasing mortality or hospitalization
Interventions to optimise prescribing for older people in care homes (Alldred et al., 2013) ¹⁴⁸ ROBIS: Low	Population: Older patients in care homes Setting: Care homes Search dates: 1966 to November 2012 Included study type/counts: 2 RCTs; 6 Cluster RCTs	1. Professional interventions (educational programs aimed at prescribers) 2. Organizational interventions (medication review services or specialist clinics, case conferencing, information and communication technology interventions)	Adverse drug events; Hospital admissions; Mortality; Quality of life; Medication related problems; Medication appropriateness; Medicine costs	No evidence of effect of interventions on adverse drug effects, hospital admissions, and mortality.
The effect of interventions to reduce potentially inappropriate antibiotic prescribing in long-term care facilities: a systematic review of randomised controlled trials (Fleming et al., 2013) ¹⁵² ROBIS: Low	Population: Older patients in care homes Setting: Care homes Search dates: Up to August 2012 Included study type/counts: 4 RCTs	1. Educational material and sessions for physicians and nurses 2. Prescribing feedback	Rate or proportion of antibiotics prescribed; Rate of antibiotics prescribed that were in accordance with recommended guidelines.	Education for medical staff may improve antibiotic prescribing but evidence was limited in this review.

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>Medication reconciliation during the transition to and from long-term care settings: a systematic review (Chhabra et al., 2012)¹⁵⁵</p> <p>ROBIS: Low</p>	<p>Population: Older patients transferred to and from long-term care settings</p> <p>Setting: Long-term care</p> <p>Search dates: 1950 to August 2010</p> <p>Included study type/counts: 4 quasi experimental design; 2 RCTs; 1 observational study</p>	Medication reconciliation interventions	Drug discrepancies; Discrepancy related ADEs; Potential drug related Problems Within 60 days of Discharge (Mortality, Rehospitalizations, Ambulatory clinic Visits, ED visit, Length of stay, Unspecified Medications, Medication errors, Quality of prescribing, Falls, Worsening mobility, Worsening behaviors, Increased confusion, Worsening pain)	All studies reported improvement associated with the intervention. However, methodological flaws limited the ability to draw conclusions about the effectiveness of these interventions.
<p>Effect of interventions to reduce potentially inappropriate use of drugs in nursing homes: a systematic review of randomised controlled trials (Forsetlund et al., 2011)¹⁴⁹</p> <p>ROBIS: Low</p>	<p>Population: Nursing home patients</p> <p>Setting: Nursing home</p> <p>Search dates: Up to April 2010</p> <p>Included study type/counts: 20 RCTs</p>	<ol style="list-style-type: none"> 1.Educational outreach initiatives 2.Educational meetings 3.Educational meetings with at least one additional intervention 4.Medication review 5.Geriatric assessment and care teams 6.Early psychiatric intervention 7.Activity program interventions for residents 	Proportion of residents with at least one fall in the past 12 months; Use of physical restraint; 'Interactional' physical restraint (force or pressure in medical examination, treatment or in activities of daily living); Mortality; Number of admissions to hospital; Number of days alive; Number of falls; Number of patients that fell	Educational interventions, alone or in conjunction with pharmacist review, may reduce inappropriate drug use. Evidence quality is low.
<p>Computerised clinical decision support systems to improve medication safety in long-term care homes: a systematic review (Marasinghe et al, 2015)¹⁵¹</p> <p>ROBIS: High</p>	<p>Population: Residents of long-term care</p> <p>Setting: Long-term care homes</p> <p>Search Dates: Up to 2014</p> <p>Included study type/counts: 7 studies (5 RCTs; 2 pre-post)</p>	Computerized clinical decision support systems	Medication safety	Five studies reported improved medication safety and 2 found no improvement
<p>Studies to reduce unnecessary medication use in frail older adults: a systematic review (Tjia et al., 2013)¹⁴⁷</p>	<p>Population: Frail older adults</p> <p>Setting: Long-term care, nursing homes and hospitals, home</p>	<ol style="list-style-type: none"> 1. Pharmacist review of drug list and diagnoses and discontinuation processes 2. Academic 	Reductions in explicitly defined unnecessary medications; Number of recommendations to	Majority of controlled studies reported significant reductions in unnecessary medications with an intervention

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS: High	care, hospice and community Search dates: January 1966 to September 2012 Included study type/counts: 15 RCTs; 4 Non RCTs; 6 Pre-post; 11 Case series	detailing to physicians 3. Staff education 4. Audit and feedback reports about medication overuse 5. Physician-led medication reviews	discontinue unnecessary medications; Reductions in composite measures of inappropriate medications that include unnecessary medications	
Interventions to optimise prescribing in care homes: systematic review (Loganathan et al., 2011) ¹⁵⁰ ROBIS: Unclear	Population: Older patients in long-term care Setting: Long-term care Search dates: 1990 to April 2010 Included study type/counts: 11 cluster RCTs; 2 RCTs; 2 controlled before-after; 1 before-after	1. Staff education, 2. Multi-disciplinary team meetings 3. Pharmacist medication reviews 4. Computerized clinical decision support systems	Proportion, number and total drug use; Composite behavioral disorders; Change in percentage of falls	Limited evidence for effectiveness, but education intervention showed the most promise.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; QOL=Quality of life

Across systematic reviews, medication review and clinician or pharmacist education were frequently the focus of interventions. Table 14 provides an estimated count of the intervention components frequently addressed across the nursing home studies included in the reviews. We note that reviews also included studies conducted in hospital or other non-nursing home settings. In addition, we classified components of interventions broadly. We recognize that elements could be categorized in multiple ways, but the table is intended to present a broad assessment of approaches addressed in studies.

Table 14. Frequently reported components of interventions described in reviews of medication errors and adverse drug events*

Intervention component	Estimated number of studies evaluating intervention component
Clinician/pharmacist education	19
Pharmacist review of medications (care facility- or home-based)	13
Information technology (CPOE, CDS, etc.)	7
Academic detailing	5
Multidisciplinary case conferences	4
Interdisciplinary care/rounding team (typically including clinical pharmacist)	3
Clinician/multidisciplinary medication review	3
Guidelines	3

*48 unique studies set in nursing homes were described in nine SERs; Studies could include more than one component; CPOE=Computerized physician order entry; CDS=Clinical decision support

The following sections address reviews that evaluated studies related to factors that may contribute to safety events in nursing homes (Table 6).

Unintentional Weight Loss, Including Dehydration

Key Points

- Two low risk of bias systematic reviews specifically addressed weight loss or dehydration outcomes. Studies were generally considered to be poor quality across reviews.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 12 RCTs and one prospective intervention study, including cohorts with comparison groups.

Overview of Reviews

One weight loss-focused systematic review examined interventions specifically designed to improve nutritional outcomes²⁷ and the other assessed interventions to prevent dehydration (Table 15).³⁸ The first included studies in long-term care facilities or nursing homes and examined non-supplementation mealtime interventions, including changes to food service, food quality improvements, dining environment alteration, staff training and feeding assistance. The review included 32 studies published between 1981 and 2012, of which 10 were RCTs, six were crossover studies, 13 were pre-post and three were cohort studies. About half of the studies included residents with dementia. The meta-analysis of RCTs showed little effect on food/caloric intake, but observational study results were mixed and generally more positive. In particular, the authors noted that provision of real-food snacks in observational research was associated with 20 to 25 percent higher caloric intake. The systematic review of interventions to prevent dehydration³⁸ included 23 studies, and examined both interventions and environmental conditions in long-term care facilities. Outcomes were hydration status or fluid intake. Interventions included greater choice and availability of beverages, increased staff awareness, and increased staff assistance with drinking and toileting.

Table 15. Overview of systematic reviews for unintentional weight loss, including dehydration

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>Increasing fluid intake and reducing dehydration risk in older people living in long-term care: a systematic review (Bunn et al., 2015)³⁸</p> <p>ROBIS: Low</p>	<p>Population: Adults aged 65 or older</p> <p>Setting: Residential, long-term nursing care or specialist dementia units</p> <p>Search dates: Up to 2013</p> <p>Included study type/counts: 4 RCTs; 3 non-RCTs; 8 pre-post; 4 crossover trials; 1 cohort; 3</p>	<p>Drinking vessel characteristics, drink characteristics, physical and social setting, institutional factors, staffing</p>	<p>Hydration status or fluid intake</p>	<p>Positive effect for multicomponent interventions, including greater choice and availability of beverages, increased staff awareness, and increased staff assistance with drinking and toileting</p>

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
	cross-sectional			
Effectiveness of mealtime interventions on nutritional outcomes for the elderly living in residential care: a systematic review and meta-analysis (Abbott et al., 2013) ²⁷ ROBIS: Low	Population: Elderly residents Setting: Long-term care Search dates: 1981 to 2012 Included study type/counts: 10 RCTs; 6 crossover; 13 pre-post; 3 cohort; 3 case-control	Food improvement (flavor enhancement), food service, dining environment, staff training and feeding assistance	Nutritional outcomes related to food intake (macronutrient or energy intake) or clinical assessments (including, weight, body composition, or functional status)	No evidence from controlled studies for benefits of food enhancement. Environmental interventions may improve nutritional outcomes.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial

Decline in Activities for Daily Living–Functional Independence

Key Points

- Five systematic reviews (3 low and 2 high risk of bias) included ADL outcomes and assessed physical rehabilitation interventions for improving ADLs among older adults. Studies across reviews were typically considered poor quality.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 16 RCTs, eight prospective intervention studies, including cohorts with comparison groups, and one pre-post study with comparison groups.

Overview of Reviews

Three reviews in this area had high risk of bias due to limitations in the reporting of methods for identifying and assessing studies.¹⁵⁶⁻¹⁵⁸ Two Cochrane reviews had low risk of bias (Table 16).^{159, 160} One Cochrane review assessed exercise programs for people with dementia and included 17 RCTs, 12 conducted in nursing home or long-term care settings (total 1,067 participants).¹⁶⁰ Six trials (289 participants) with significant unexplained heterogeneity assessed effects of exercise on ADLs in nursing home residents specifically. The standardized mean difference between exercise and control arms was 0.68 (95% CI: 0.08 to 1.27, p=0.02), favoring the exercise arm; however, the trials were considered to be of low quality due to a lack of blinding of outcome assessors, indirectness, and imprecision. A second Cochrane review evaluated progressive resistance strength training, defined as exercises with resistance from weights, exercise machines, or other materials that is progressively increased as strength increases.¹⁵⁹ The review included 121 trials with 6,700 participants, and control arms typically included other forms of exercise as well as usual care. Nine of 121 studies included nursing home residents (426 participants), and studies assessed changes in general physical function. Most studies were of poor quality, with high attrition and a lack of blinded assessments. Overall, the review found some support for physical rehabilitation training compared with no treatment control arms in improving strength, ability to walk, ability to climb stairs, and ability to get out of a chair. Adverse events were poorly reported across studies, and differences between other

types of exercise programs and physical rehabilitation training were not significant. Another review focused on RCTs of physical rehabilitation in long-term care facilities, and found that reported effects were small across 68 studies.¹⁵⁶ A fourth review included RCTs and quasi-experimental studies, and included studies up to the year 2009. The focus of this review was on manual handling during transfers on and off furniture and both patient-level and staff-level outcomes (e.g. sustainability).¹⁵⁷ A final review addressed the effect of exercise interventions designed to reduce falls on individuals participation in life roles, defined as “involvement in life situations” such as employment, using transportation, social interaction, and civic life and included 19 RCTs.¹⁵⁸

Table 16. Overview of systematic reviews for decline in activities for daily living–functional independence

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Exercise programs for people with dementia (Forbes et al., 2015) ¹⁶⁰ ROBIS: Low	Population: Over age 65 with dementia Setting: Any care setting Search dates: Up to 2013 Included study type/counts: 17 RCTs	Exercise programs	Cognition; Activities of daily living; Neuropsychiatric symptoms; Depression; Mortality	Exercise was beneficial for ability to perform ADLs in 6 trials but evidence quality was considered very low. No evidence of benefit on cognition, neuropsychiatric symptoms or depression.
Physical rehabilitation for older people in long-term care (Crocker et al., 2013) ¹⁵⁶ ROBIS: Low	Population: 60 or older Setting: Long-term care home or hospital Search dates: Up to 2011 Included study type/counts: 67 RCTs (including 19 cluster design)	Physical Rehabilitation program interventions designed to maintain or improve physical function	Function in performing ADLs (e.g., feeding, dressing, bathing, etc.)	Small improvements in physical functioning as measured by Barthel Index, Functional Independence Measure, Rivermead Mobility Index and walking speed
Progressive resistance strength training for improving physical function in older adults (Liu et al., 2009) ¹⁵⁹ ROBIS: Low	Population: Aged 60 or older Setting: Institution or home residence Search dates: Up to 2008 Included study type/counts: 121 RCTs	Progressive resistance strength training	Physical disability including ADLs, and physical domains from HRQOL	PRT improved physical ability, gait speed, and getting out of a chair.
Do exercise interventions designed to prevent falls affect participation in life roles? A systematic	Population: Older adults Setting: Any Search Dates: Up to	Exercise interventions for fall prevention	Participation in life roles	Exercise interventions to reduce falls may improve participation in life roles in older adults. Majority of

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score review and meta-analysis (Fairhall et al., 2011) ¹⁵⁸ ROBIS: High	May 2010 Included study type/counts: 96 RCTs (19 measured participation)			these studies were conducted in community settings.
The Impact of Manual Handling on nursing home Resident Mobility During Transfers On and Off Furniture (Taylor et al., 2011) ¹⁵⁷ ROBIS: High	Population: Nursing home residents Setting: Long-term aged care and/or nursing homes Search dates: 1994 to 2009 Included study type/counts: 5 RCTs; 3 quasi experimental studies; 2 systematic reviews	Safe manual handling programs Physical activity interventions	Residents' ability to transfer on or off furniture; Resident health-related quality of life; Staff manual handling practice improvements; Sustainability of manual handling practice change; Intervention costs	Functional training was associated with improved resident mobility and transfer abilities.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; ADL=Activities of daily living; HRQOL=Health-related Quality of life; PRT=Progressive resistance training

Fecal and Urinary Incontinence, Including Constipation

Key Points

- Across four systematic reviews (3 high and 1 unclear risk of bias), studies were of mixed quality and typically reported outcomes associated with prompted voiding interventions, toileting programs, pharmacologic approaches, and behavioral-focused approaches to improving urinary and/or fecal continence.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified seven RCTs, one prospective intervention study, including cohorts with comparison groups, and one pre-post study with comparison groups.

Overview of Reviews

Four systematic reviews were identified focusing on prevention and management of urinary or fecal incontinence in the elderly (Table 17).¹⁶¹⁻¹⁶⁴ Two reviews included only studies conducted in nursing homes and evaluated toileting programs, prompted voiding, use of medical interventions, and use of incontinence pads. The most recent was published in 2012 and included studies up to 2010. The review was rated as having a high risk of bias due to potential publication bias and limited assessment of included studies. The review included 33 studies, of which 11 were RCTs, and focused on outcomes of interventions to improve urinary or fecal incontinence.¹⁶¹ The review reported moderate benefits associated with prompted voiding and toileting programs, inconsistent evidence for drug therapy, and a need for more evidence on multifaceted behavioral interventions. Another paper published from this review reported on additional outcomes related to the management of incontinence including economic data, skin care, exercise, staff quality, and promotion of continence.¹⁶⁴ The review highlighted that

programs to improve continence are associated with increased costs (increases in average daily costs/incontinent resident, increased nursing costs, and decreased laundry costs in one older study) but that staff attention to incontinence and hydration issues remains clinically important. The other review is fairly out of date as it was published in 2008. It included timed voiding and medical interventions and provided data from 14 RCTs. Another AHRQ review, conducted in 2007 and considered out of date, included both studies in community dwelling individuals and nursing home residents.¹⁶³ The review included four studies in the nursing home, focused primarily on reducing the progression of urinary incontinence (2 studies) or urinary and fecal incontinence (2 studies). Interventions included prompted voiding, strength training, and care pathways.

Table 17. Overview of systematic reviews for fecal and urinary incontinence

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Factors with the management of incontinence and promotion of continence in older people in care homes (Flanagan et al., 2014) ¹⁶⁴ ROBIS: High	Population: Older adults (age > 65) Setting: Care homes Search Dates: 1966 to 2010 Included study type/counts: 9 studies (2 RCTs; 1 crossover; 3 non controlled comparative studies; 3 pre-post studies)	Intervention studies with associated factors in management of incontinence	Factors associated with management of incontinence	Factors to consider include economic data, skin care, exercise studies, staff quality promoting voiding adherence, management of dehydration and incontinence
Systematic review of care intervention studies for the management of incontinence and promotion of continence in older people in care homes with urinary incontinence as the primary focus (1966-2010) (Flanagan et al., 2012) ¹⁶¹ ROBIS: High	Population: Care home residents with urinary incontinence Setting: Care home Search dates: 1966 to 2010 Included study type/counts: 42 interventional studies (33 with UI as primary outcome, including: 11 RCTs; 7 cohorts; 1 uncontrolled pre-post; 14 case series)	Bladder training, prompted voiding, timed voiding, habit training, functional incidental training, prompted waking program Adjunct drug therapy (oxybutynin, estrogen and progesterone)	Incontinent wet checks; Incontinence episodes	Prompted voiding reduces daytime UI No improvements shown with nighttime PV or waking program techniques. Oxybutynin might provide small additional benefit as adjunct to PV
Prevention of urinary and fecal incontinence in adults (Shamliyan et al., 2007) ¹⁶³ ROBIS: High	Population: Adults Setting: Long-term care and community Search Dates: NR Included study type/counts: NR	NR	Prevalence and risk factors for urinary and fecal incontinence	Prevalence increased with age and functional dependency. Individualized management programs can improve continence in long-term care facilities but difficult to sustain.
Treatment interventions in nursing home residents with urinary incontinence: a systematic review of randomized trials (Fink et al., 2008) ¹⁶² ROBIS: Unclear	Population: Nursing home residents Setting: Nursing home Search dates: 1985 to 2008 Included study type/counts: 14 RCTs	Behavioral Pharmacological (antimuscarinic medications Propantheline, Procaine hematoporphyrin, Oxybutynin, oral estrogen plus progesterone, and behavioral: prompted voiding or functional	Incontinent wet checks; Appropriate toileting ratio	Prompted voiding and prompted voiding with exercise associated with short-term improvement in daytime UI. Oxybutynin may provide small additional benefit when used with prompted voiding.

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score		incidental training)		No role for oral estrogen in treatment

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; NR=Not reported; UI=Urinary incontinence; PV=Prompted voiding

Depressive Symptoms

Key Points

- Two systematic reviews (both low risk of bias) included studies with mental health and depression outcomes. Studies in both reviews were small and of limited quality.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 38 RCTs, seven prospective intervention studies, including cohorts with comparison groups, and six pre-post studies with comparison groups.

Overview of Reviews

One low risk of bias review in this area was specifically focused on combining psychiatric and nursing home care to reduce psychiatric symptoms and improve global functioning (Table 18).¹⁶⁵ The review found benefits on severe behavioral problems among residents receiving multidisciplinary services.¹⁶⁵ A second review of six RCTs assessed depression-related outcomes following multiple behavioral and psychosocial interventions for people with dementia.¹⁶⁶ The review noted some positive effects of psychological treatment vs. usual care on depression in a meta-analysis (standardized mean difference: -0.22 [95% CI: -0.41 to -0.03]).

Table 18. Overview of systematic reviews for depressive symptoms

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score				
Psychological treatments for depression and anxiety in dementia and mild cognitive impairment (Orgeta et al., 2014) ¹⁶⁶	Population: Older adults with dementia Setting: Any setting Search dates: Up to 2013 Included study type/counts: 6 RCTs	Psychological interventions including, cognitive behavior therapies, relaxation training, psychodynamic, interpersonal, counselling	Depression or anxiety	Positive effect of psychological treatment on depression and on clinician-rated anxiety (but not on self-rated or carer-rated anxiety)
ROBIS: Low				
Efficacy of integrated interventions combining psychiatric care and nursing home care for nursing home residents: a review of the literature (Collet et al., 2010) ¹⁶⁵	Population: Nursing home residents needing psychiatric and nursing home care for somatic illness or dementia combined with psychiatric disorders or behavioral problems	Integrated, multidisciplinary interventions combining psychiatric care with nursing home care	Severe behavioral problems; Measures of cognition, aggression and agitation	Beneficial effects shown for short-term mental hospitalization. 7 studies reported positive results from multidisciplinary approaches, including medical, psychiatric and nursing

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score				
ROBIS: Low	Setting: Nursing home Search dates: Up to 2008 Included study type/counts: 4 RCTs; 1 cohort; 3 case series			interventions.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial

Overuse or Inappropriate Use of Antipsychotic Medications

Key Points

- Four systematic reviews (2 low and 2 high risk of bias) addressed antipsychotic use or overuse. The quality of studies across reviews was generally low.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified five RCTs and one prospective intervention study, including cohorts with comparison groups.

Overview of Reviews

Increasing understanding of an association between use (and overuse) of antipsychotics and morbidity and mortality among the older adults has led to studies focusing on identifying and reducing inappropriate antipsychotic use in this population. Four systematic reviews included antipsychotic or psychotropic use as an outcome; three had low risk of bias,¹⁶⁷⁻¹⁷⁰ and one low risk of bias review was published in 2014, included 22 studies (Table 19).¹⁶⁹ Studies focused on educational programs (n=11), in-reach services (n=2), medication review (n=4) and multicomponent interventions (n=5). The review provided short-term evidence for effectiveness on the outcome of reducing overall prescribing but the authors suggest that longer-term research is necessary. Another meta-analysis of four RCTs was a Cochrane review of psychosocial interventions, also focusing on prescribing as the outcome.¹⁶⁸ Four cluster-randomized studies were included; all of them were of complex interventions of educational approaches. Overall, the quality of the studies was moderate and all demonstrated reductions in antipsychotic medication use. Another recent review evaluated both published training manuals for person-centered care programs targeting psychiatric symptoms in people with dementia in nursing homes as well as clinical trials of the programs codified in manuals.¹⁷⁰ The review assessed effects on reducing antipsychotic medication use, among other outcomes, and included three studies evaluating the effects of staff and resident education on antipsychotic use. The overall risk of bias of this review was high.

In another systematic review and meta-analysis focused on the effects of medication review or educational interventions on the appropriate use of psychotropic drugs in long-term care settings, five studies specifically targeted antipsychotics.¹⁶⁷

Table 19. Overview of systematic reviews for overuse or inappropriate use of antipsychotic medications

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Interventions to reduce inappropriate prescribing of antipsychotic medications in people with dementia resident in care homes: a systematic review. (Thompson-Coon et al., 2014) ¹⁶⁹ ROBIS: Low	Population: Dementia patients Setting: Care homes Search dates: Up to 2013 Included study type/counts: 22 studies (6 RCTs; 5 non randomized; 11 pre-post with no control group studies)	Educational programs, in-reach services, medication review, and multicomponent interventions	Antipsychotic medication use	Short-term Beneficial effects seen in 9 of the 11 studies with most robust design-reductions in prescribing levels between 12-20% No long-term data were available.
Psychosocial interventions for reducing antipsychotic medication in care home residents. (Richter et al., 2012) ¹⁶⁸ ROBIS: Low	Population: Dementia patients Setting: Care homes Search dates: Up to 2011 Included study type/counts: 4 Cluster RCTs	Educational and training, multidisciplinary team meetings	Antipsychotic medication use	All four studies reported a decrease in proportion of residents with antipsychotic drug use or reduction in days of drug use
The disconnect between evidence and practice: a systematic review of person-centered interventions and training manuals for care home staff working with people with dementia (Fossey et al., 2014) ¹⁷⁰ ROBIS: High	Population: People with dementia Setting: Care homes Search Dates: NR Included study type/counts: 7 studies (RCTs or non-RCTs)	Person-centered intervention and training manuals for dementia care staff	Neuropsychiatric outcomes (agitation, depression, and total neuropsychiatric inventory) and antipsychotic drug use	Person-centered interventions improved agitation and reduced use of antipsychotics. Only 4 training manuals had been evaluated in clinical trials. Many interventions and training manuals are used despite lack of demonstrated effectiveness.
Psychotropic prescribing in long-term care facilities: impact of medication reviews and educational interventions (Nishtala et al., 2008) ¹⁶⁷ ROBIS: High	Population: Age 65 and older Setting: Long-term care Search dates: 1980 to 2007 Included study type/counts: 7 RCTs; 4 controlled trials	Medication review and/or education	Proportion of residents using one or more psychotropic drugs in long-term care	Five studies on hypnotic drug prescribing showed decrease in use post-intervention (MA pooled OR 0.57, 95% CI 0.63 to 1.04) Prevalence of antipsychotic prescribing post intervention was not significant (OR 0.81 95% CI 0.63 to 1.04)

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; NR=Not reported; MA=Meta-analysis; OR=Odds ratio; CI=Confidence Interval

Moderate to Severe Pain Management

Key Points

- One systematic review (high risk of bias) addressed pain outcomes and included studies of variable quality.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified eight RCTs and one pre-post study with comparison groups.

Overview of Reviews

One systematic review¹⁷¹ focused on pain management among nursing home residents (Table 20). Interventions ranged from decision support to systems interventions, and the studies had markedly uneven quality. Generally, process outcomes were used rather than resident-centered outcomes in the primary literature. The search end date was in 2007, and the review had high risk of bias.

Table 20. Overview of systematic reviews for moderate to severe pain

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
Pain management interventions in the nursing home: a structured review of the literature (Herman et al., 2009) ¹⁷¹ ROBIS: High	Population: Nursing home residents Setting: Nursing home Search dates: 1982 to 2007 Included study type/counts: 8 RCTs; 9 single-group repeated measures design; 4 cohort	Pain management – actor modifications, systems, treatment modifications, and decision support	Medication use, patient report	Uneven quality of research with limited number of high-quality studies. Process endpoints were used as surrogate measures without evidence showing that they lead to pain reduction.

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial

Influenza Vaccine

Key Points

- One systematic review (low risk of bias) assessed vaccination for staff of long-term care facilities. Studies included in the review had high risk of bias.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 11 RCTs and one pre-post study with comparison groups.

Overview of Reviews

One Cochrane systematic review evaluated the benefits of vaccinating health care workers who work with the elderly in institutions (Table 21).¹⁷² The search included studies published through March 2013 with outcomes including serologically proven influenza, pneumonia and

deaths from pneumonia. High risk of bias in the original studies left some doubt as to the benefits of vaccination.

Table 21. Overview of systematic reviews for influenza vaccine

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions Thomas et al., 2013) ¹⁷² ROBIS: Low	Population: Health care workers with regular contact of aged 60 and older Setting: Long-term care facilities Search dates: Up to 2013 Included study type/counts: 4 cluster RCTs; 1 cohort	Influenza vaccine	Influenza or complications (respiratory tract infection, or hospitalization or death due to RTI)	No evidence that vaccinating health care workers prevents influenza or complications in individuals over age 60 in long-term care facilities

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; RTI=Respiratory tract infection

Pneumococcal Vaccine

Key Points

- No systematic reviews specifically evaluated this area.
- Our searches for intervention studies conducted in nursing homes identified one RCT.

Use of Physical Restraints

Key Points

- One review (low risk of bias) reported findings on restraint use associated with educational interventions in five RCTs with poor methodologic quality.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified three RCTs, one prospective intervention study, including cohorts with comparison groups, and one pre-post study with comparison groups.

Overview of Reviews

One Cochrane systematic review assessed interventions to reduce the use of physical restraints among older adults in long-term geriatric care (Table 22).¹⁷³ The search went up to September 2009 and included both educational and system-level interventions. The report included five RCTs and concluded that there is insufficient evidence supporting the use of educational interventions for nursing staff to reduce the use of physical restraints. Three studies reported reductions in restraint use while one reported an increase and another reported no changes in the intervention group.

Table 22. Overview of systematic reviews for physical restraints

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>Interventions for preventing and reducing the use of physical restraints in long-term geriatric care (Mohler et al., 2011)¹⁷³</p> <p>ROBIS: Low</p>	<p>Population: Elderly patients in long-term care</p> <p>Setting: Long-term care</p> <p>Search dates: Up to September 2009</p> <p>Included study type/counts: 5 RCTs</p>	<p>Educational interventions</p> <p>Organizational interventions, including policy changes</p> <p>Interventions providing restraint alternatives</p> <p>Other interventions or combination</p>	<p>Primary outcomes: Number or proportion of residents with at least one PR; Prevention of PR; Reduction of PR</p> <p>Secondary outcomes: Type of PR; Duration of PR use; Prescription of psychotropic drugs; Residents' and caregivers' quality of life; Adverse effects of the interventions employed; Duration of effect of the interventions; Injuries and deaths during the study period</p>	<p>Study results were inconsistent in 5 small low-quality RCTs. Insufficient evidence to demonstrate effectiveness of education interventions to reduce physical restraint use.</p>

ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; PR=Physical restraint

Catheter Left in Bladder

Key Points

- We did not identify any systematic reviews specifically addressing this issue.
- Our searches for intervention studies conducted in nursing homes identified one recent RCT that evaluated an intervention for long-term indwelling catheters in the bladder.

Other Interventions Including Staffing Models

Key Points

- Three systematic reviews (low risk of bias) addressed multiple interventions and outcomes including person-centered care and falls prevention, case conferences and challenging behavior, and special dementia care units and depression and other outcomes. Few studies were included in each review, and studies typically had moderate to high risk of bias.
- Four systematic reviews (high risk of bias) addressed staffing specifically and reported on multidisciplinary models and advanced practice nursing models. Studies included in reviews typically had high risk of bias.
- Our searches for intervention studies conducted in nursing homes and published after the latest search date of the reviews outlined above identified 42 RCTs, seven prospective intervention studies, including cohorts with comparison groups, and four pre-post studies

with comparison groups that addressed multifocused interventions (e.g., falls, delirium, incontinence issues).

Overview of Reviews

Multicomponent Approaches

Interventions and key outcomes assessed in three additional reviews did not fall cleanly into one of the categories described above; rather, these reviews addressed multiple interventions and outcomes (Table 23).¹⁷⁴⁻¹⁷⁶ One review addressed person-centered care interventions implemented in nursing homes.¹⁷⁵ Interventions were multifaceted and included environmental modifications, social interaction, staffing changes, continuity of care, and changes in interaction and leadership approaches, and most of the seven included studies were pre-post design. Studies were considered to be of lower quality, with potential confounding factors and heterogeneity. In general, outcomes related to communication, social interaction, satisfaction, and approaches to care improved across studies, but risk of falls increased in the intervention arms.¹⁷⁵ A second review addressed case conferences as a tool for handling challenging behaviors in nursing home residents with dementia and included seven studies (4 RCTs) of generally poor quality that precluded firm conclusions.¹⁷⁴ A third Cochrane review assessed “special care units” for individuals with dementia and behavioral problems.¹⁷⁶ The review defined special care units as “a set of related interventions including features such as a unique staffing pattern, special programming, or environmental designs” and included eight studies (all cohort studies or nonrandomized trials). Outcomes assessed included use of physical restraints and psychotropic drugs and depression. Studies showed no significant effects of special care units on psychotropic drug use and small, short-term positive effects on restraint use. Depression also improved in special care units in one study; however, the authors note that all studies were small and settings were variable.

Table 23. Overview of systematic reviews for additional interventions

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
ROBIS score Effects of person-centered care on residents and staff in aged-care facilities: a systematic review (Brownie et al., 2013) ¹⁷⁵ ROBIS: Low	Population: Aged-care residents Setting: Aged-care facilities Search dates: January 1995 to October 2012 Included study type/counts: 1 cluster RCT; 6 pre-post with or without control group	Person-centered interventions (environmental enhancement, social stimulation and interaction, leadership and management changes, staffing models)	Impact of The Eden Alternative on: Residents' psychological status; Functional status; Infection rates; Levels of depression; Satisfaction with staffing care Impact of The Green House model on: Residents' satisfaction; Facility-specific person-centered care approaches on the capacity of staff to deliver individualized care; Perception of	Two studies showed person-centered care was associated with increased rate of falls. Eden Alternative improved resident's boredom.

Title, Author, Year of publication ROBIS score	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
			their job characteristics; Residents' views about quality of care; Levels of agitation in residents with dementia	
Case conferences as interventions dealing with the challenging behavior of people with dementia in nursing homes: a systematic review (Reuther et al., 2012) ¹⁷⁴ ROBIS: High	Population: Dementia patients Setting: Nursing homes Search dates: Up to September 2011 Included study type/counts: 4 cluster-randomized; 2 quasi-experimental design; 1 pre-post	Case conference A theme-centered, solution-oriented approach	Institutionalization or death; Challenging behavior; QOL; Burden/stress of nurses; Self-efficacy; Staff nursing performance	4 out of 7 studies showed improvements in challenging behavior. Need for well-designed intervention studies.
Special care units for dementia individuals with behavioural problems (Lai et al., 2009) ¹⁷⁶ ROBIS: High	Population: People with dementia or Alzheimer's disease or related disorders Setting: Special care units Search Dates: Up to 2007 Included study type/counts: 8 non-randomized studies with controls	Special care units compared to traditional nursing units (nursing homes, SNFs)	Agitated or disruptive behavior Secondary outcomes: Physical restraint use; Psychotropic medications; Mood; Well-being; Quality of life	There were no RCTs available. The non-randomized studies do not provide strong evidence of the benefit of special care units.

QOL=Quality of life; ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; SNF = skilled nursing facility

Staffing Model Interventions

Four systematic reviews focused on the benefits of different staffing models in nursing homes and long-term care (Table 24).^{121, 177-179} Two focused on the role of advanced practice nurses. Results overall were mixed, with interdisciplinary care and advance practice nursing approaches associated with some positive effects, but a paucity of quality evidence.

Table 24. Overview of systematic reviews for staffing interventions

Title, Author, Year of publication	Population, Setting, Search Dates, Included study type/counts	Interventions Included	Outcomes Assessed	Conclusions
<p>Nurse staffing impact on quality of care in nursing homes: a systematic review of longitudinal studies (Backhaus et al., 2014)¹²¹</p> <p>ROBIS: Low</p>	<p>Population: Nursing home residents</p> <p>Setting: Nursing home</p> <p>Search dates: January 2007 to April 2013</p> <p>Included study type/counts: 20 studies (study design NR)</p>	<p>Nurse staffing levels and professional staff mix</p>	<p>Pressure ulcers; Infections; Activities of daily living decline; Fractures; Urinary incontinence; Pain; Weight loss; Disruptive behavior; Restraints; Catheterization; Hospitalization; Administrative outcomes</p>	<p>Inconsistent results for the impact of increased nursing staff and quality of care.</p>
<p>Effectiveness of staffing models in residential, subacute, extended aged care settings on patient and staff outcomes (Hodgkinson et al., 2011)¹⁷⁸</p> <p>ROBIS: Low</p>	<p>Population: Residents or patients aged 65 years or older</p> <p>Setting: Residential, sub-acute, and extended aged-care facilities</p> <p>Search dates: NR</p> <p>Included study type/counts: 1 interrupted time series; 1 controlled before-and-after study</p>	<p>1) Primary care model versus team-nursing model. Primary care defined by: 24 hour accountability by one nurse; case method of assignment; direct communication between caregivers and a shift in emphasis in the head nurse role to a facilitator. Team nursing was a hierarchical system. 2) Resident-oriented model versus usual care</p>	<p>Incidence of pressure ulcers, falls, medication errors and adverse events; Validated quality of life measurement; Tranquility-agitation; Vitality; Personal control; Performance of activities of daily living</p>	<p>No conclusive evidence on primary care or resident oriented care based on two studies.</p>
<p>A systematic review of the effectiveness of advanced practice nurses in long-term care. (Donald et al., 2013)¹⁷⁷</p> <p>ROBIS: High</p>	<p>Population: Advanced Nurse Practitioners</p> <p>Setting: Long-term care settings</p> <p>Search dates: 1966 to 2010</p> <p>Included study type/counts: 1 RCTs; 2 non-RCTs; 1 cohort</p>	<p>Use of Advanced Practice Nurses</p>	<p>Depression; Urinary incontinence; Pressure ulcers; Restraint use; Aggressive behaviors</p>	<p>Advanced practice nurses improve some health indicators, including depression, urinary incontinence, pressure ulcers, restraint use, and aggressive behaviors.</p>

Systematic review of Interdisciplinary Interventions in nursing homes (Nazir et al., 2013) ¹⁷⁹ ROBIS: High	Population: Nursing home residents > 60 years old Setting: Nursing home Search dates: January 1990 to August 2011 Included study type/ counts: 27 RCTs	Various interdisciplinary approaches, including integrated care and team meetings	Psychotropic reduction; Behavior presence; Restraint reduction; Antipsychotic use decrease; Number of falls; Number of prescriptions; Proper antibiotic usage; Nutritional status; Weight decrease; Incontinence; Mobility	18 out of 27 RCTs showed positive effects. Successful interventions included participation by the primary care physician, pharmacist, and team communication.
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ROBIS=Risk of Bias in Systematic Reviews; RCT=Randomized controlled trial; NR=Not reported; QoC=Quality of Care

Primary Studies Published Since the Included Systematic Reviews

We identified a total of 239 unique new comparative studies evaluating safety-related interventions in the nursing home (Table 25). Across all areas, many were RCTs, suggesting the presence of a substantial research base. We did not assess the quality of these studies; that would be the appropriate work of a new systematic review.

Table 25. Overview of new studies of nursing home safety interventions

Safety Area Addressed	Randomized controlled trial (RCT)	Prospective intervention studies, including cohorts with comparison groups	Pre-Post studies with comparison groups
Falls with injury	16	3	1
Pressure ulcers	16	3	2
Infection, including healthcare-associated infection (HAI), urinary tract infection (UTI), and antibiotic stewardship	7	1	0
Medication errors and adverse drug events (ADE) (e.g., delirium), including inappropriate medication use and polypharmacy	2	4	0
Unintentional weight loss, including dehydration	12	1	0
Decline in activities of daily living (ADL) –functional independence	16	8	1
Fecal and Urinary incontinence, including constipation	7	1	1
Depressive symptoms	38	7	5
Overuse or inappropriate use of antipsychotic medications	5	1	0
Moderate to Severe pain	8	0	1
Influenza vaccine	11	0	1
Pneumococcal vaccine	1	0	0
Physical restraints	3	1	1
Catheter left in bladder	1	0	0
Multi-focused Interventions	42	7	4

GQ4a. What is the uptake of evidence-based nursing home interventions beyond individual test sites? What are the most important barriers and facilitators to uptake of successful interventions?

Research Evidence

As summarized in GQ3, a number of studies have been summarized in systematic reviews on overuse of antipsychotic medications, urinary incontinence, delirium, ADL decline, and medication errors. However, fewer studies exist on preventing pressure ulcers, falls, and unintentional weight loss, and it appears more conflicting. Even good systematic reviews have come to contradictory conclusions. Moreover, for some outcomes, in many cases, studies have measured only intermediate process outcomes, without providing evidence on safety measures. Perhaps due to inconsistencies and lack of consensus in the literature, uptake of specific interventions appears to be limited. That said, a fairly large body of primary literature published after the latest systematic reviews is available, and this new literature could inform an update of existing findings for many safety areas in the nursing home care setting.

Barriers to Uptake

Three primary barriers to uptake appear to be a) a lack of consensus around what level of adverse events may be acceptable and thus a target for interventions; b) lack of evidence that Federally collected quality measures serve to encourage changes in practice and c) lack of implementation data from effective interventions that would support uptake.

First, limited evidence exists on expected levels of different safety outcomes, given that some degree of decline and associated clinical events will certainly occur in this vulnerable and complex population. For example, in one RCT of feeding assistance, even when oral food and fluid intake and body weight significantly improved for the majority of enrolled long-stay nursing home residents, some residents (10%) continued to lose weight despite optimal nutritional care quality.²⁹ A zero prevalence of unintentional weight loss may not be an appropriate expectation and nursing homes could more confidently adopt practices from the research with realistic targets.

Second, the current practice of comparing nursing homes on quality measures to identify variability (e.g., which homes are in top 10th percentile for falls) assumes that variability in rates is a true reflection of differences in quality of care or safety practices. Empirically, however, this connection has not been established for many specific quality measures, staffing levels and other outcomes and warrants consideration. For example, hospital readmissions have been associated with the CMS collected staffing indicator, but not other quality measures.¹⁸⁰

Third, most intervention studies that have demonstrated positive outcomes do not report the resource requirements needed for implementation, and this lack of information makes it difficult to achieve the uptake of even successful safety interventions. In the few studies wherein the necessary resources, particularly staffing, have been reported (e.g., urinary incontinence, weight loss, hydration, ADL decline), resources often exceed the typical operating capacity of the facility, suggesting that modifications of effective interventions may be necessary to support uptake.¹⁸¹⁻¹⁸³

Beyond resource needs for intervention implementation, many intervention studies do not document the specific care processes that led to the outcome improvements or otherwise include measures of intervention process fidelity. This lack of specificity limits the ability of other facilities to replicate the findings in care practice and also likely contributes to mixed results in the published literature.

Ultimately, the field should coalesce around specific safety measures in long-term care, and this may entail a more nuanced consideration of safety outcomes rather than a simple binary none/any approach. Research to identify the incidence and prevalence of targeted safety outcomes under defined care conditions for this frail, medically-complex population would better inform achievable safety standards for nursing homes. Finally, we encourage researchers in this field to document key implementation details such as care processes and related resource requirements that would support replication and uptake.

GQ4b. What major areas for future research remain regarding resident safety in nursing homes?

Encourage Implementation Research

Many studies in this field do not include standardized, independent measures of safety outcomes, complete information on the care processes thought to be related to those outcomes, and details about the staffing resources (number, time, equipment) necessary to provide the interventions. Because these components are so often lacking in the literature, it is difficult to determine to what extent mixed results in prior systematic reviews for various outcomes are attributable to a lack of an intervention effect or lack of intervention fidelity or lack of resources to support the intervention. The weaknesses in implementation science contribute to the weak/mixed evidence base, a dearth of incentives to change care practice, and questions about staffing resource requirements necessary to improve outcomes as well as what outcomes are even achievable. These are inter-related issues that should be addressed in future studies.

Develop Consensus Around Common Outcomes

As noted above, specific outcome performance standards (e.g., absolute rather than relative performance) for acceptable quality of care and safety in nursing homes are missing and this likely impedes implementation of interventions with demonstrated effectiveness. One way to achieve performance standards is to actively develop consensus among experts in the field. Another is to encourage the conduct of implementation science to help identify what is achievable under controlled conditions, and describe fully the resources and circumstances needed to achieve those outcomes. Finally, better characterization of implementation research also could provide important clinical information about the resident characteristics that may modify effectiveness of given interventions.

Specific research questions include:

- What are the maximum achievable outcomes (e.g., fall or pressure ulcer incidence rate reduction) when specific care processes thought to be related to the outcomes are implemented with high fidelity?
- What resident characteristics modify intervention effectiveness such that clinically meaningful criteria can be used to best target interventions?

Empirically Assess the Role of Performance Monitoring Approaches

Outside of the inspection process and recent targeted chart review protocols used in IOG studies,³ most research to date has relied on self-reported information from nursing home facilities. Because discrepancies have been noted between self-reported and externally collected data, validation research as well as direct observation studies would be informative.^{3, 37, 46, 184}

As an example of changes in practice that may improve available data, CMS has now instructed survey staff to increase their audits during the survey process.^{185, 186} In particular, questions that have arisen about the accuracy of self-reported staffing information that is part of the current 5-Star reporting systems, staffing data submitted to CMS will soon be based on nursing home payroll data in lieu of facility self-report. This has the potential to provide additional and important data for research.

Research questions include:

- What auditing approaches are most efficacious and effective more broadly for verifying the accuracy of adverse event reporting in nursing homes?
- Does the effectiveness of such auditing differ by frequency of the audits?

Rigorously study the role of staffing models and levels in achieving safe environments

Published data about the staff time required to provide optimal care are limited to only a few care areas; thus, future studies should be used to determine whether specific staffing models are associated with specific outcomes. Concurrently, effectiveness studies should report details about staffing that can be used to assess this potential modifier of effectiveness..¹⁸¹⁻¹⁸³ An increased focus on implementation science in the evaluation of nursing home interventions could provide a basis for understanding the role of staffing models in the future and would, in fact, reduce the need for minimum staffing standards in nursing homes by providing more nuanced information about models that affect outcomes. Many nursing homes nationwide currently report total staffing levels that are consistent with expert consensus recommendations (Table 2). However, staffing levels still vary significantly, with little evidence to suggest that any particular model is optimal for improving quality and safety.^{118, 187} A potential reason for variability in staffing levels is the absence of reliable and empirically established models describing an optimal level and mix of staffing resources based on resident acuity.

If there is to be a move toward acuity-based staffing models, significantly more implementation research should be done, including explicitly linking the time needed to provide care with available staffing resources and with the quality of care provided. Although the RUGs system used to reimburse skilled nursing care identified the time spent providing care as reported by facility staff, it did not take the next step of assuring that care was provided in a manner consistent with federal regulations that define acceptable care quality. As noted earlier in this report, a comparison between RUGs expected staffing levels and those reported via Nursing Home Compare showed that 59 percent of nursing homes have actual staffing levels that fall below the recommended levels based on this system.¹²³

Research questions include:

- What are the staff-time requirements associated with interventions known to prevent adverse events?
- Given staff time requirements, are any staffing models more efficient and effective than others in practice for preventing adverse events?

- How can labor resource data be converted into an information system useful for planning the number and skill mix of staff necessary to prevent adverse events?

Better understand what works for optimal staff training and management

At a very practical level, methods of training and managing staff should be studied and reported, including operational research. It is conceivable that managers may not be cognizant of safety lapses in their facilities or the best approaches to training staff, documenting care, or implementing programs to improve safety. Studies suggest that there are also potential problems in the hospital setting related to care inconsistencies and documentation. Specifically, recent studies from multiple hospital systems have shown that both nurses and patients report frequent omitted care, particularly care related to pressure ulcer and fall prevention (e.g. repositioning and mobility assistance). Hospital nurse staffing levels have been shown to be the primary predictor of care omissions and there is no reason to believe that this is not also a potential issue in nursing homes^{188, 189}. Rigorous evaluations of both staff training and management models would provide needed information for broader implementation. Potential examples include web-based approaches that would be continually available to new staff. Programs that do exist, including the Quality Assessment and Performance Improvement (QAPI) framework, should be rigorously evaluated.

Relatedly, an intervention that currently lacks rigorous evaluation is use of point of care documentation systems, which are commercially available, that may provide timely methods to identify care frequency and care omissions. A second solution that does not require technology is the use of standardized observational tools by managers to intermittently monitor daily care processes related to adverse events. Recent studies have demonstrated that standardized observations can be used by both nursing home staff and surveyors to monitor nutritional care quality and resident-centered care practices^{46, 52, 190-194} but both technological and non-technological approaches to management improvement need to be rigorously evaluated in future studies.

Research questions include:

- What is the effectiveness of various staff training and management models for improving staff ability to provide optimal care?
- What is the role of direct observation in multicomponent approaches to staff feedback?
- What is the effectiveness of point-of-care documentation systems for reducing adverse events?
- What is the role of care process information (collected either through technology or standardized observations) for improving staff performance?
- What are the costs of implementing new care process documentation systems or the staff training and management models based on the data generated by these systems?

Rigorously Evaluate Person-centered Care

The evidence base assessing person-centered care approaches is new, albeit growing. Given potential trade-offs between personal freedom (a common tenet of these approaches) and safety, good evaluations are needed to better understand the role and optimal implementation of person-centered care. Conversely, studies to evaluate clinical interventions to improve resident health status and other clinical outcomes also should consider the potential risks and benefits related to

residents' quality of life and wellbeing. Future studies also should define the specific daily care processes related to person-centered care and objectively measure associated outcomes to allow such models to be replicated in other facilities.

Research questions include:

- How does daily care differ between facilities based on person-centered care models and other models (e.g. are residents offered more choices in their daily lives?)
- How do daily care differences relate to adverse events?

Study Approaches to Managing Polypharmacy

Polypharmacy is common in both hospitalized older patients and nursing home residents and can be associated with a number of adverse events and other poor clinical outcomes. We do not know, however, to what extent it can be improved for this medically complex population, while managing challenging clinical conditions. For example, older adults discharged from the hospital to post-acute care (SNFs) have an average of more than 13 medications and new medications are prescribed during their hospital stay.^{63, 195} This high number of medications per patient may increase the probability of adverse medication-related events and also is related to multiple geriatric syndromes associated with safety outcomes (e.g., falls, urinary incontinence, weight loss, delirium, depression).^{63, 196-199} Literature on medication-related adverse events alludes to some of these issues. However, evidence that medications can be safely reduced for this frail older population or if improved health outcomes related to safety can be achieved with medication reductions is lacking for older hospitalized patients discharged to SNF but also for those discharged to home.⁹⁰ Future research should evaluate interventions related to polypharmacy and medication reductions and should assess appropriate medication management to optimally balance reducing unnecessary prescriptions while also effectively managing clinical needs.

Research questions include:

- Is there evidence that polypharmacy is associated with adverse events in the nursing home population?
- What interventions to safely reduce the number of prescribed medications for hospitalized older adults discharged to SNF and subsequently to the nursing home or home demonstrate promise?

Establish what lessons can be learned from Hospital Safety for Older Patients

The assumption that effective hospital safety interventions to target nursing home residents exist and are transferrable to the nursing home setting is untested. Furthermore, analyses of hospital discharge records highlight a lack of documentation for problems related to safety and experienced by geriatric patients in the hospital.^{61, 63, 66} A separate comprehensive literature review of hospital-based safety practices specifically as they relate to older patients could identify aspects of hospital care and the discharge process that warrant improvement.

Research questions include:

- What is the evidence that hospital-developed and based interventions to improve safety are transferrable to the nursing home population?
- What barriers to generalizability exist?

- What modifiers of effectiveness exist in the nursing home setting that are the same or different than those in the hospital?

GQ4c: In what ways is the field of long-term care changing such that resident safety interventions may need to adapt to a new environment, and what additional challenges do these changing conditions bring to increasing long-term care patient safety?

Population Shifts and Clinical Challenges

Our Key Informants suggested that several shifts in the target population are occurring rapidly and require that safety interventions and related research adapt as part of future efforts to improve safety outcomes. These include increases in the psychiatric needs of nursing home residents, individuals with HIV-AIDS living longer lives and moving to nursing home care, and the care of aging prisoners. Perhaps most significantly, a greater proportion of older adults who are higher functioning with fewer care needs are moving into assisted-living facilities (ALFs), rather than nursing homes. As a result, the nursing home population is becoming more medically complex with higher care needs. As this shift occurs, the dominant paradigm may change from curative to palliative care, which has the potential to affect definitions of target safety outcomes as well. Also inherent in this shift is a need to focus increasingly on educating families and residents to make informed treatment decisions such that a resident's life expectancy and quality of life are strongly considered.

Assisted-Living Facilities (ALFs) and Dementia Care within ALFs

ALFs are not only the fastest growing segment of elderly congregate living but ALFs also house residents with multiple ADL and cognitive impairments.^{200, 201} Some state-level regulations govern ALF staffing, but these vary by state and are less restrictive than those for nursing homes. In particular, the significant growth in dementia care services within ALFs makes this segment of the ALF population similar to those with dementia in nursing homes.^{201, 202} This similarity suggests that safety issues for those with dementia in the ALF care setting may be comparable. One of the biggest challenges in ALFs is the lack of standardized quality or safety data; thus, the extent of care quality and/or safety problems in this care setting is largely unknown, with only a few studies examining ALF care quality.²⁰¹⁻²⁰⁴ Future research in this area is needed for multiple reasons.

First, the number of ALFs is growing with an estimated 36,000 facilities serving over one million older adults nationwide.²⁰⁰ A recent nationwide survey of 31,100 ALFs revealed dementia as one of the most prevalent chronic conditions.²⁰¹ As least partially due to the prevalence of dementia, 74 percent of ALF residents require caregiver assistance with one or more ADLs, such as bathing (72 percent), dressing (52 percent), and toileting (36 percent).²⁰¹ Moreover, a longitudinal study showed that ALF residents and long-stay nursing home residents both experienced significant and comparable decline in their ability to independently perform ADLs.²⁰³ Functional decline is a quality indicator for both short- and long-stay nursing home residents, and evidence suggests that optimal care can prevent decline.¹⁸³ Thus, safety issues related to functional decline may be similar in both the nursing home and ALF care settings.

Because the ALF industry began as a hospitality industry, it is also likely that measures related to person-centered care and quality of life are also equally applicable across settings.

One Key Informant who represented the ALF industry noted that resident acuity is increasing in this population, and current ALF staffing, both in terms of number and skill set, is likely inadequate to meet future needs. Specific data about staffing in ALFs is not widely available because, unlike nursing homes, ALF staffing data are not publicly reported. Neither ALF nor nursing homes have validated systems in place to match resident acuity with staffing needs and/or staff competency. Thus, there is a risk that many ALFs do not have a sufficient number and/or the appropriate type of staff to provide necessary care in a safe manner. Some of the safety concerns raised by Key Informants included medication errors, at least partially due to the skill set of the staff responsible for medication management (e.g., use of medication aides as opposed to licensed nurses); falls; and accurate assessments of clinical conditions (e.g., delirium, dehydration, depression) in the absence of licensed nurses with this skill set to support timely treatment. As the ALF population continues to grow, including the presence of dementia care services within ALF, it is becoming critically important to have defensible data to identify the staffing resources necessary to meet care needs and maintain safety. Fewer data are available about resident acuity and staffing in the ALF care setting relative to nursing homes, and the absence of specific staffing regulations for ALFs creates the potential for more safety problems. Thus, future research should address care quality, safety, and related resource requirements to care for the ALF population, particularly those with dementia in ALF.

Summary and Implications

Summary of Patient Populations and/or Safety Issues not addressed in this Technical Brief

Several areas are notably missing in this report. We did not review safety issues associated with home health care services, although these services are growing rapidly. We also did not review data on hospice and palliative care services, although we note the need for attention here and reflect these services as part of the continuum of care in Figure 1. We also excluded transitional care units in hospitals and inpatient hospital rehabilitation facilities, as well as VA community living centers (although some of the cited research may have included VA sites, we did not examine this setting specifically). Finally, as noted, assisted living facilities may be the fastest growing setting for the care of increasingly vulnerable residents but these were not the focus of our report. That said, it was challenging to determine which studies in the systematic review literature were truly conducted in nursing homes or may have taken place in residential care settings, given inadequate descriptions of settings as well as different terminology used, especially internationally.

Next Steps

A large and growing body of literature on nursing home safety exists, as evidenced by the available literature for all GQs in this brief. As noted, however, the quality of that research is mixed. In a number of areas that have existing systematic reviews, enough new studies are available that an update may be warranted. In addition, the existing evidence reviews often failed to report what we consider to be a critical issue – namely the source of data and types of studies included therein. In terms of primary research, we have laid out not only the current state of the

literature, but recommendations for future research. Those recommendations, available in GQ4, could lead to substantially stronger evidence in the area of nursing home safety.

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